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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

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| Proceeding | 91237066 |
| Party | Defendant<br>Rory F. Krieger |
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| Submission | Answer |
| Filer's Name | Rory Krieger |
| Filer's email | rfkone@earthlink.net |
| Signature | /Rory Krieger/ |
| Date | 01/11/2018 |
| Attachments | TM HISTOLOGY OF DERMACAREWAND.pdf.pdf(111547 bytes )<br>1-11-2018 TM DISCLOSURE MOTION.pdf.pdf(317665 bytes ) |

# 12-6-17 BACKGROUND & HISTOLOGY OF **DermaCareWand™**

**Describe the significant problem your company is trying to address.**

For the past 35+ years, Applicant/Defendant Rory Krieger, has been an out-patient to family doctors and numerous dermatologists. During that time, he has experienced innumerable botched "mole, wart and skin tag removal treatments." My "front row seat" has provided me with unique insights and first-hand insights. I have experienced all treatment methods healthcare professionals could dish out, including DIY methods. Gravely dissatisfied with the results, in 2014 I decided it was time to develop a device that raises the standard of care, treats patients more thoroughly where post-op scaring or re-treatments are greatly reduced. That is the "why" I created **DermaCareWand™**. Currently, this physical wand device is undergoing a pre-clinical review through CCTSI at Anschutz Medical Campus, Aurora Colorado. We are also seeking physician mentors and business advisors in the UC Health system to assist us in bringing this product to market in late 2018/early 2019.

On a human level, we all have skin in the game regarding visible epidermal growths that appear at conspicuous locations as we age. These skin growth lesions can range from benign to pre-cancerous. They also represent social stigmata, career impediments and levels of psychological embarrassment. To this end, the standard of care in treating lesions should engender a high priority, with regard to this disruptive device we are pledging to UC Health confirmation of our proof-of-concept. This device and what it can do is more about fixing a nagging, socially embarrassing problem you--and I face today and tomorrow. The investment dollars will flow when we reach out to local communities and in-network hospital providers. In short, this is a problem we can fix together, using the regulatory and engineering runway I have already developed over the past 3+ years.

FYI: I have already filed for intellectual property protection on this device (2015) with the USPTO.gov. I have also met personally with the FDA, discussing the merits of this very device. Their review was positive and encouraged development with a local research hospital. In short, the **DermaCareWand™** Opportunity is in the fight to end a war between sub-par family doctor triage, and patients who require performance, transparency and accountability from personalized healthcare. An opportunity for greater personalized healthcare at lower costs exists under this device.

**DermaCareWand™** (DCW) is an enabling technology in the life-sciences sector of healthcare. Value based, under clinical review at Anschutz Medical Campus (Aurora, Colorado), this device is intended "*... to improve clinical results for physicians who perform out-patient dermatological triage and cryosurgical treatments.*" A device intended to raise the bar in Ux engagement, with greater recurring revenues and improved patient results.

**WHAT PROBLEM ARE WE SOLVING? QUALITY DERMATOLOGICAL HEALTHCARE**

"Quality of care" is a vague term. The best answer is also contingent on whom you ask. The American Dermatological Association (ADA) offers guidelines for quality of care, yet the methodology used by physicians to remove your particular skin growth...is pejoratively at their discretion. Cut, burn, dissolve, freeze or rub-in an ointment? It's up to them, not the patient. Can there be a lapse in judgement or sub-par treatment causing in scarring injuries? Of course!

When patients call out their physician, doctors are quick to point the finger and blame everyone but themselves. "Are all providers equally skilled to use a syringe, take a biopsy of tissue with a scalpel knife, apply abrasion or negative-pressure treatments to clear a canthus nodule? No. Is cryosurgery always the "preferred methodology" to minimize scarring on a patient? Again, no it is not. Your skin tags and mine are unique, and a singular method is not the one size fits all panaceas.

Think of the last time you went in for a skin tag to be removed, "Were you satisfied with the results?" Did you expect keloids and scarring left behind on your clear skin?" Was a scar an acceptable result or was the suffering and embarrassment you paid for, the lesser of two evils? For doctors and patients, this is a cold-war. "Do you think most patients see poor results as a 'truth or dare' proposition?" Again, the answer is a resounding "yes."

**Point #1:** Abuse/botched and misuse of that doctor/patient privilege is an existing burden within this niche industry. Malpractice results in higher insurance deductibles. It's a fungible industry that is searching for a solution. And industry where consumers vote with their feet. Some of us push-back by boycotting our local dermatology clinics, others drop off the radar.

As more of us baby-boomers reach full maturity in our 80s and 90s, the need for skin care is increases exponentially. Moreover, if poor triage experiences is the status quo and people are sharing their experiences and commenting on SnapChat, Periscope, Twitter, and Facebook etc. doctors will lose more and more market shares. Patients will go elsewhere ISO DIY, OTC and other personalized healthcare remedies.

**Point #2:** Healthcare physicians...have a casual, if not troubled relationship with accurately reporting cryosurgery CPT-coded procedures. So it is with conviction that I, after 36+ years of experience as a patient in their clinics, decided I had enough! So in the summer of 2014, I sought to break-down the silos of enigma, unmask their charade & expose abuses in procedural dysfunction. As a byproduct, clean-up the back-office billing malfeasance with respect to CPT-coding (Medicaid) in cryosurgery. Most of that can be corrected with the "right tool for the job." Enter our novel medtech device, **DermaCareWand™.**

**OUR PRODUCT: DermaCareWand™ IS HABIT FORMING**

**DermaCareWand™** is a novel, hardware as a service (HaaS) and disruptive medtech device. Secured by USPTO filed IP, we own a patent-pending lock on this break-through technology. First and foremost, this product is differentiated by our FDA engineering strategy. We took a holistic approach to visible lesion removal. Our "better mouse-trap" uses a simple ergonomic hand-held wand that fits into the palm of your hand. No electricity. No use of ozone or LED radiation gadgetry or intensity vibration metering dials. No IVD, no biologics, no combination or constituent parts, none of that. As a single-use-device (SUD), our tool is lab-coat pocket sized, weighs-in less than 1oz., 8.75" long, 1/8" thick, blue, curved like shoe-horn with orifices.

Finally, call us out. Allow us to prove that **DermaCareWand™** is the right tool for the job. We believe performance technology is a balance of key priorities. **DermaCareWand™** allows for better decisions, better results, with fewer regrets." As an enabling technology, the Mark seeking Notice of Registration to Certificate of Registration is intimately tied to the medical community, and the new performance based healthcare model; one that supports our moms and dads, brothers and sisters and people of all stripes. With preclinical hurdles still on the horizon, we expect to begin selling this device to medical distributors by late 2018.

**In a few sentences, describe your main value proposition.**

**DermaCareWand™** is a life-sciences, digital medtech device, providing anatomical modeling & surgical templates to greatly improve the standard of care for physicians treating dermatological skin lesions that are both benign, and precancerous.

**Is your solution product or service-based?**

Product-based (physician extender). Fits in today's performance-based healthcare paradigm.

**How does your product or service address the problem?**

**DermaCareWand™** treats visible epidermal skin lesions using the "quadruple aim" method, and our proprietary anatomical Metric Index Template (MIT) model.

It provides: 1. **Better outcomes**, 2. **Lower costs**, 3, **Patient satisfaction** and 4. **Provider impact**. Using next-generation technologies, this device is unique in the field of plastic surgery and general hospital tools. It fits into a standard FDA classification, has no constituent or combination parts, IVD, CBER biologics or the use of direct or passive radiation. For a closer discussion, ABC-PRESENTS requires signage of our NDA (under seal to TTAB), not Opposers.

In conclusion, if the TTAB would like to learn more about the **DermaCareWand™** nomenclature, please contact us, and request our NDA. Include your legal agent name, title, ph. # and address. Thank you. Rory Krieger, CTO of ABC-PRESENTS, LLc. 919-628-3386 (c). Email: rfkone@earthlink.net.

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**To:** Mr. Andrew Baxley, TTAB Interlocutory Attorney **01-11-2018**

**TM Motion: Pre-Disclosure Description of DermaCareWand™.**

Re: Case/Opposition No. 91237066; ICTV BRANDS, INC. v ABC-PRESENTS, LLC.

**Dear Mr. Baxley,**
Thank you for participating in our first Discovery Teleconference on 12-7-2017. Many thanks. This letter was originally sent to you on 1-8. This letter brings our case/discussions/discoveries up to date.

Today's letter refers to that Discovery Teleconference, and email documents I, the Applicant/Defendant sent hours before it began. Entitled, "12-7-2017 Discovery Conference Letter" those documents and photos preface our upcoming Disclosure Discussion, and should be referred to with equal weight to those included herein. I have included that letter as an attachment, should you need to refer to it.

Moreover, we received a printed snail mail follow-up letter from you dated 12-11-2017. In it, you Mr. Baxley included case history, and was adamant that the Opposer and Applicant pursue an ACR, over a traditional process. On page-6 you wrote, *"...they should notify the above-signed Interlocutory attorney as soon as possible to schedule a telephone conference to further discuss how they want to go forward with ACR."* This letter, is that notification by Applicant. Will you consider attending, via teleconference, our upcoming Disclosure discussion on 1-13-2018, as you did before on 12-7-2017?

As the Applicant/Defendant in this proceeding, my staff and I whole-heatedly agree with your wish to pursue the ACR. To that end, let us schedule a Disclosure Discussion Teleconference before the Saturday January 13, 2018 deadline.

Furthermore, the following relates to handwritten notes taken during our 12-7-2017 teleconference, after you Mr. Baxley, signed-off. From those notes, my team has stitched-together a list of Motions for the Opposer. Excerpts which were verbally communicated to Kevin Crosby in part, and to which they (K. Crosby, J. Carrino) agreed to abide by and submit (in dossier form) to you as TTAB Interlocutory Attorney, and Applicant (Rory Krieger), in-advance of our next court directed Disclosure teleconference deadline. Below, is our Motion request of 1-3-2018, asking the Opposers to "Make their Case"... proving a **Derma wand®** item, is materially the same in-use, indications, function, channels of use, performance, regulatory design as **DermaCareWand™**.

Below, is a standard medtech "To-Do" list for "specification developers" of medical devices, seeking FDA certification to sell/market and license a medical device in the U.S. There are many moving parts to this: design regulations, safety standards, feedback test results among others...must be tested and validated showing verifiable results for scrutiny.

The Applicant's medical device (aka **DermaCareWand™**) is following this gauntlet of high FDA standards. In this Motion, we are asking the Opposers to prove their (Dw) item, also rises to the same set of high standards; a prerequisite to comparing ICTV Brands, Inc. **Derma Wand®** (Dw) item, to our **DermaCareWand™**. Kevin, John? Think of this as checking off the boxes and making your best case. Where your opposition claims against us are met by verifiable industry standards, dates and current references (for which you are obligated to address). It's your best shot at proving, beyond a shadow of a doubt, IF and HOW that frivolous Notice of Opposition letter (showing claims numbering 1-26), stands-up to the sanitizing light of the fact finders (via point-by-point medical industry standards). In effect, the Opposers entire case hinges on: show and tell proof,

voracity, and verification of answers rendered through this ACR Motion (Q&A list below). It will either rest their Notice of Opposition (Case No. 91237066), or solidify Plaintiff's demise, forcing a *motion to dismiss/ opposition cancellation*. Those are the terms as we verbally agreed, over the phone, on 12-7-2017.

As the Applicant, ACR allows us this *fact-proving prerogative*. We further stipulate that nothing short of complete documented answers to each point below, are strictly followed. We also require you to provide us with a printed, paper-bound dossier of your due diligence findings. The TTAB requires an electronic version of the same. *Complete this homework assignment*...and have it back to both of us before our 1-13-2018 scheduled Disclosure deadline, as the contents therein will be referenced during that teleconference. As a matter of course, your dossier will be vetted by the Applicant and/or independent 3rd party medical verification source(s), including the TTAB themselves. In your research, Do not include any similar devices to the (Dw), nor past 510(k) references from similar (or derivative devices) that DO NOT CORRESPOND TO/NOR EXACTLY MATCH (Dw) FDA serial number(s), HCPCS (CPT-coding), ISO Regs., of your item's Medicaid Reimbursement registration #'s.

***Kevin, John...Ready to play hard-ball?*** **Let's begin!**

1. Does your (Dw) item fulfill all requirements set-forth by the FDA? [See Reference A-1]
2. Provide contact name(s) and phone number(s) of (Dw) Regulatory "RAPS" liaison.
3. Provide FDAs recognized Standard of Care, for which the (Dw) uses oxygenating, and LED light generating (with vibrator control dial), is an effective anti-aging, skin system that produces an anti-aging cure or improves patients with facial crow's feet, forehead wrinkles, sagging facial, chin/neck, inner-thigh as a non-surgical face lift option". Refer to ICTV Brands, Inc. link in [Reference A].
4. Provide (Dw) "Indications of Use" (per FDA usage).
5. Provide US-based, university clinical results showing direct Indications of Use to the advertisement campaigns by ICTV Brands, Inc. late-night TV and Internet infomercials.
6. Document HF design through cycle of: inputs, in-use testing, and validation outputs.
7. Document (Dw) TPLC (Total Produce Life-Cycle Report).
8. Provide the FDA product code (class and sub-classification) for the (Dw) item is registered.
9. Provide the FDA approval letter, showing date, signature and serial number (on official FDA letterhead) when the (Dw) item became registered in the U.S, and available for sale as a bona fide medical device.
10. Provide documents showing removal of facial, neck, etc. wrinkles as the "Standard of Care" for which the FDA has also approved for same use, the (Dw) as a bona fide, regulated, approved medical device.
11. Provide documents showing FDA design inputs and outputs histology
12. Provide (Dw) registration and accepted ISO certifications. [References B]
13. Provide documentation showing: timeline of R&D, engineering strategy. [Reference C].
14. Provide cGMP manufacturing R&D of (Dw) item (foreign or domestic).
15. Provide documented FDA.gov regulatory strategy for which the Derma wand (Dw) item was conceived.
16. Provide pre-clinical testing and HF (human factor) results on willing volunteers.
17. Provide pre-clinical testing results in animal case studies.
18. Provide post-clinical CAPA,
19. Provide documented case studies where an attending physician, non-paid by ICTV Brands, Inc. provides a reputable, patient procedure per FDA Indications of Use, etc. [Reference D].
20. Provide a copy of FDA Application on file for said item (not a derivative or item by a different Mark).
21. Provide five (5) voluntary test subjects who were treated by a (Dw) item in 2017.

22. Provide a list of 25 in-network physicians who perform "nip and tuck" plastic surgery who endorse, vouch for and willingly discuss using (Dw) as a verifiable, non-surgical option producing the SAME RESULTS as surgical procedures (as indicated in ICTV Brands Infomercials) on the record. [Reference D]
23. Provide pre-clinical testing, showing verifiable test results according to AAD epidermal clinical guidelines, in Human Factors (HF) and animal test results.
24. Provide appropriate use guidelines (drawing parallels to established FDA Draft Guidance Guidelines.
25. Provide verifiable case-based, physician-patient treatment documented post-operative results, showing the efficacy of the (Dw) item,
26. Provide above documents that are not suppressed by HIPPA laws (physician-patient secrecy).
27. Provide CPT Insurance and Reimbursement Code list, showing the range of procedures and post-operative, case-study results.
28. Provide CPT 2018 billing schedule.
29. Provide registered owner name(s) of (Dw), registered Medicaid Reimbursement Certificate,
30. Provide cGMP Engineering strategy as it complies with (CDRH) Centers for Devices and Radiological Health) and DICE (Division of Industry, Consumer Education).
31. Provide American Academy of Dermatology AAD.org member/physician advocates who use, support and advocate the Derma wand in their day-to-day clinical practices.
32. Provide a list of 50 In-Network physician testimonials by licensed MDs who regularly use (Dw).
33. Provide sub-set of above who are in-network physicians employed by large and small hospital chains who, as part of their approved procedural regiment, openly (Dw) as alternative to plastic surgery.
34. Provide full contact names and address of 50, in-network dermatological surgical clinics that currently purchase and solicit for use, the (Dw) item from authorized Medical Device distributors.
35. Provide 20 medical peer reviews in recognized medical publications, endorsing (Dw) item.
36. Out of Network physician testimonials or derivative devices similar to the (Dw) item are not acceptable (as they are subject to kick-back bribes and illegitimate endorsement).

In summary, the above "ACR lite" checklist, in its totality, is standard medical device evaluation procedures used by the FDA, CDRH, CBER, DICE and Medicaid to verify, approve and certify a "spec developer" proposed device meets all the high standards of FDA criteria for design, engineering, regulatory strategy:
FDA Part 21 CFR 820.30, FDA ISO 13485/2016, FDA safety 14971, ISO 9001, cGMP, CMS.gov reimbursement etc. within the new performance-based healthcare paradigm. In this vein, the Applicant's bid for **DermaCareWand™** will be compared point-by-point, against a plethora of unsubstantiated specious claims made by GrayRobinson, a legal team defending the owner(s) of a Derma Wand® item. Providing all these data points entirety to the TTAB & Applicant, will (in our opinion), achieve one of two ends:

1. Support Opposers 10-5-2017 Notice of Opposition Claims, or
2. Abdicate their entire Notice of Opposition and claims in this case, causing a Motion to Dismiss.

The FDA is a clinical-based, results-based federal agency enacted to safeguard physicians and the public they serve. Applicant in this case, seeks to expose the histology of Opposers Notice of Opposition claims. Specifically, the regulatory structure surrounding legitimate FDA approved devices, from dubious, deceptive, snake-oil products. Gizmos promoting false promises hawked by fly-by-night profiteers to low-educated, gullible, easily deceived consumers. In this case, aging, face-sagging females who are desperately ISO of redemption; insipidly leaping at any captivating fantasy they see on TV/OTC to recapture their youth by the purchase of fantasy-filled tchotchkes offering dubious claims, unrealistic promises, for pennies on the dollar as compared to plastic surgeon administered chin, neck, face-lifts, etc. at ("Nip & Tuck") healthcare rates.

It is our hope the Opposers will conduct and submit a careful & thorough due diligence report. Submitting a copy to both the TTAB and their accused Applicant. This will work because, only a comprehensive fact-finding dossier will support, and exonerate Opposers claims, including a mountain of suspicion surrounding marketing tactics used by ICTV BRANDS, Inc. vs an onerous set of minimum standards required by the FDA, CMS.gov, ISO regulatory bodies, and fact-based, performance based safety standards, etc. in today's healthcare ecosystem.

IF...the Opposers can meet that high water mark above, we can then move on to the next step. Address speculation claims that **DermaCareWand™** promotes its compound Mark "*...with a likeliness of confusion*". Opposition team has yet to reply to Applicant's Motion on 12-7 to submit a written corroborating dossier.

To this end, in our review of the Notice of Claims, Opposer, according to said 12-7 Motions, elected to provide detailed, point-by-point, results based evidence in support of each claim set forth in their October 5, 2017 Notice of Opposition (91237066). Applicant has denied a number of Opposers substantive and salient claims in the "Accept or Deny Letter" (emailed to Opposer and the TTAB on 11-4 and 11-5-2017, respectively).

In addition, PRIOR to and during the Discovery Teleconference of 12-7-2017, let it be known that Applicant and Opposing attorney Kevin Crosby, agreed in advance (via email and a telephone conversation) that an out of court, negotiated settlement is preferred to a protracted litigious trademark battle. That said, Mr. Krieger asked Mr. Crosby to introduce and connect him with "...a member of ICTV Brands, Inc. M&A team (merger and acquisition) being a "heavy weight agent"). A "person of capacity" able to negotiate fiduciary decisions out of court for ICTV. During a separate, pre-discovery phone conversation, Kevin addressed this issue by telling Mr. Krieger (I'm paraphrasing here)... "He (an agent from ICTV Brands, Inc.) will contact you next week, as that person (the one I have in mind) was contacted, but is travelling over-seas and is currently unavailable".

Being mindful of time-lines, Applicant has waited patiently. The purpose of which is obvious; giving both parties ample lead-time to acquire corroborating docs and make a Disclosure Dossier Presentation.

FYI, over a month later, on 01-09-2018, Applicant received a phone call @ 9am MST from ICTV Brands, Inc. CEO, Mr. Kelvin Claney. In our 44 minute conversation, Mr. Claney threatened me "...to take this lawsuit out 5 years, and cost you a lot of money" as he said. He also disregarded our 12-7 Motion to support their case.

Furthermore, Mr. Crosby, in an email response (following our morning phone discussion) on 12-7-2017, emailed the Applicant this promising message (screen shot below):

**From:** "Kevin P. Crosby" <Kevin.Crosby@gray-robinson.c... [Edit Address Book]
**To:** RF Krieger <rfkone@earthlink.net>
**Cc:** Andrew Baxley <Andrew.Baxley@USPTO.GOV>, "'jcarrino@carrinolaw.com'" <jcarrino@carrinolaw.com>
**Subject:** RE: 12-6 Written Settlement Draft on behalf of ICTV Brands, Inc.
**Date:** Dec 7, 2017 9:53 AM

Mr. Krieger,

I won't have time to draft a settlement proposal before our call, but should be able to by tomorrow. Do I take it that it should be along the lines of my e-mail to you of November 10th?

**Kevin P. Crosby | Shareholder**
**Florida Bar Board Certified in Intellectual Property Law**
**GRAY | ROBINSON**

401 East Las Olas Blvd., Suite 1000 | Fort Lauderdale, Florida 33301
**T:** 954-761-8111 | **F:** 954-761-8112 | **D:** 954-761-7510
E-mail | Website | Bio | vCard **Facebook** | **LinkedIn** | **Twitter**

The email above, for which Kevin is referring, was his own November 10th letter to Applicant; offering a pecuniary pay-off, forcing this TM opposition into default. The pay-off (as his story goes) promised Applicant a TM registration micro-entity check as "hush-money". A bribe, forcing Applicant to choose another Mark, perhaps one of several he suggested in his email bribe. Promoting their agenda, withdraw of **DermaCareWand™**, dashing our legitimate claim to a Certificate/Notice of Allowance by the TTAB. Case study has proven this tactic benefits the Opposing team who then registers the abandoned Mark, absorbing it into their "protected portfolio." FYI? We respectfully declined Kevin's offer. **[Opposer Failed at Bribery]**

By all accounts the above "failures to execute" raise many red-flags about the credibility of Kevin Crosby and his Opposing staff. Moreover, the Opposer has taken liberties to "casually throw loaded hand-grenades" at-will both here and there, without producing a single shred of evidence to prove the voracity of their claims. Talk is cheap. Unsubstantiated Discovery-meeting promises... are as worthless as a vote for Hillary Clinton. Suggesting the other side is hiding a smoking-gun or flawed-hasty casework. It is our hope, given the remaining time before our 1-13-2018 Disclosure deadline; Opposers will follow ethical legal practices and produce the requisite due diligence dossier to legitimize their case. As of 1-11-18, no dossier was received.

HISTORY SUPPORTING **DermaCareWand™** R&D: Our research began in 2014. Based on similar medical devices and regulated bodies (NAMSA), the **DermaCareWand™** Mark (DCW) was conceived from over 36+ years of poor outpatient triage treatments from "healthcare professionals". Botched treatments left behind scarring (keloids) from tags, warts, moles, etc. that were poorly treated. The **DermaCareWand™** medtech device was therefore designed by a patient (me) for the physician, to produce accurate, safe patient post-op results. Many FDA regulatory, pre-clinical testing, Human Factor (HF) feedback, and ISO standards encompass a long litany of Quality Management Systems (QMS/QRS); standards that dictate inclusion into Medicaid reimbursement and FDA certification. The litmus tests, which we are following, are built into our proof of concept design. To date, our medtech device still requires more university guided & NIH refinements.

That said, our device shows a strong likelihood of developing into a value-based, medical commodity used by licensed physicians (not OTC consumers). Early on (March 10, 2016), we sat down and met directly with the FDA in Baltimore, MD. Their panel of eight Ph.Ds, gave us a positive feedback for future FDA approval. Follow-on discussions included, Pre-Submission (Q-Sub) classification, discussions over: CAPA, CDRH, DICE, etc. Our R&D work was focused to achieve maximum classification clearances, cGMP, eQMS, etc. documentation, etc. including clinical design discussions with three (3) regulated bodies inclusive. Applicant has diligently pursued a merit-based strategy that fits squarely in today's fact-based dermatological healthcare ecosphere. Our performance-based, evidence-based device has become common law in peer reviews, and inseparably linked.

Our patent pending "Lesion iD technology" and tuned 1-to-1 physician interface sets a new safety standard for cryosurgical dermatological clinics, the **DermaCareWand™** also fits into both FDA regulatory and "CMS determination" (reimbursement). Our IP, product branding, pending TM and scope of healthcare adoption is conservatively valued between, $3.5 to $7 million USD. A firm projection based on its: FDA & CMS "parallel regulatory & engineering strategy." On 12-9-2016, Rory Krieger made a board presentation to a team of MDs at the University of Colorado Anschutz Medical Campus (CCTSI). Their feed-back summary/appraisal is attached. Using this Mark, we have already established common law usage.

On schedule for market launch, our projection shows the device may not be FDA certified for sale in the U.S. until late 2018 to early 2019. SalesForce projections, market adoption, patient feed-back will dictate moving on to the Canadian, the EU and into Japan, our prime target market. Currently, this medical device will be under review by the National Institutes of Health (NIH), and is a candidate for pre-clinical HF mentorship and

testing at a local Anschutz Medical Campus (AMC). **DermaCareWand™** fits into a well-known FDA regulation: FDA 21 CFR Part§878.4800 "Manual surgical instrument for general use." Regulations are high, and it is our pledge to meet those high, but fair standards. In the US, the world of medicinal biologics, implants, treatments, cardio-heart pumps, pioneering De Novo treatments as well as more benign medical devices (such as ours), everything we do from the design to concept to clinic, is scrutinized in a QMS/QRS data file, for which the FDA can and will conduct an unannounced walk-in audit within the first 5-years of business. Nothing is taken lightly in this industry. Patient safety, production standards, safety and efficacy is all baked-in the cake.

**Briefly, *"What service does DermaCareWand™ provide? How does it do it?"***
We begin by stating our cherished, **Indications of Use**:
***"A hand-held, epidermal lesion containment system, forming a topical-isolative-capture of cutaneous skin morphologies. Unique patented cryofirewall template treats: Actinic Keratosis, Canthus, External Genital Warts-Human Papilloma Virus (EGW-HPV), moles, peduncle hanging-tags (finger tags) and polyups, plantar warts, scars, Seborrheic Keratosis, etc. from adjacent virgin tissue, enabling high-cure rates. A critical-task tool for cryosurgical triage physicians using croyprobes, vaporized sprays or liquid nitrogen (LN2)."***

**ABC-PRESENTS, LLC., principle register/owner of DermaCareWand™** is in the business to develop a high standard, FDA-certified, Medicaid reimbursed, disruptive medical device. Used as a physician extender by MDs in controlled environments of a medical clinic, for treating outpatients having: skin tag(s), moles, warts, pre-cancerous and many types of cancerous lesions/morphologies. The shape is similar to a 9" shoe horn with a plethora of exacting, morphological matching orifices where lesions are press-sealed, and ablated using LN2.

FYI: skin tags may appear on any part of the surface of the body (skin), but most typically exist in areas where epidermal surface skin rubs against itself. **DermaCareWand™** uses a proprietary mixed-methods approach (within FDA Part 21 CFR 820.30) to target, circumferentially seal, and safely treat (via clinical cryosurgical processes) using LN2 (liquid nitrogen or directed spray-on Freon, CryoPen™ or similar Freon-means), causing "destruction by necrosis" (tissue death) to benign and pre-cancerous lesions/morphologies. Below is a short-list of common skin lesions this device treats:

- A.K/S.K (Actinic Keratosis, Seborrheic keratosis)
- Axillae (armpits)
- Curettes (fleshy and/or dark raised tags around the eye socket, cheeks, nose, neck, forehead)
- EGW/HPV, external genital warts, human papilloma virus
- Eyelids (hanging finger tags)
- Peduncle Tags (under the breasts, armpits, inner thigh "hanging tags"
- Upper chest, hand/arm flat warts (colored or fleshy neutral)
- Neck tags (dark raised "necklace growths")
- polyps, plantar warts, cysts
- Plantar Fasciitis (painful, inward-growing bottom of foot warts), etc.

Skin tags can be benign (and pre-cancerous) tumors on our skin. Often, they cause few symptoms, unless repeatedly rubbed or scratched, as may happen with clothing, jewelry, or when shaving. Very large skin tags may burst under pressure. Many are pre-cancerous (basal/squamous cell lesions), developing into cancerous growths and requiring more intensive oncological treatment strategies. Skin tags are composed of a core of fibers and ducts, nerve cells, fatty cells covering the visible, epidermal layer of the skin (epidermis).

**"INDICATIONS OF USE"** (is an FDA phrase) that encompasses a range of inputs, design verifications, and output validations. Read more about this at: https://www.fda.gov/MedicalDevices/default.htm
**DermaCareWand™ IS FOR DERMATOLOGICAL PHYSICIANS, TREATING SKIN LESIONS/MORPHOLOGIES**
Our device is not for vanity, low-educated consumers who are desperately grasping for gizmos they hope will turn-back the clock of father time or make their sagging face, neck, arms, breasts or thighs appear perky or youthful again. Our device does not plug into the wall. Has no AC plug-in or battery powered components, or a tubular shaped body design. It does not use LED lights, does not emit electronic radiation, ozone, nor does it produce electrified shocking means to "regenerate, spur collagen production" in the subdermal skin layer. Our device does not use a dial to increase oxygenating electrified intensity. It does not indicate, nor vaguely purpose to treat aging skin, sagging skin, crows-feet/laugh lines by the eyes, face, neck, thighs, etc., nor promise to slow or reverse "the appearance of..." cosmetic consequences related to "sun exposure, smoking, bad genes, stress aging, etc." Our device does not promise "vanity cosmetic youthful fantasies, nor make any such claims (or hints) about revitalizing or removing "the appearance of weathered skin" caused by age!

Clearly then, the **Indications of Use of DermaCareWand™**, are governed by design engineering, FDA regulation, Medicaid reimbursement CPT-coding and several ISO standards. Manufactured only by cGMP (good manufacturing practices meeting high FDA standards) and subject to "482 medical device audits".

Therefore, the **DermaCareWand™** medical device, is 180° unrelated--to all opposition claims of Indications of Use, size, channels of commerce, methods etc. as put forth by Derma wand—ICTV Brand, Inc. attorneys in this opposition case! Their false descriptions, false designations, dilutions, misrepresentations and a host of specious ambiguities (as seen throughout the Opposer's Notice of Opposition claims), cannot ever be substantiated. Those claims will be proven false—when and IF the Opposers respond completely to Applicant's Motion for a documented, verifiable dossier on each point we challenge in that Motion.

Furthermore, Applicant is not currently selling this *proof-of-concept device* (nor can we do so) until we achieve all FDA regulatory requirements (for sale in the US). Once we achieve that high-water mark and achieve TTAB Trademark Certificate of Allowance for our junior Mark, we will likely utilize our 6-month Intent to Use 1(b) grace period, then renew it to extend our intent to use status, before everything is lined-up and certified.

**Regulations Apply**: the **DermaCareWand™** fulfills FDA requirements as a "Class-1, hospital general surgery, and single-use device (SUD)." Our Intellectual Property (IP) is also patent pending. Should the TTAB wish to view our provisional patent, please request our NDA through the appropriate TTAB channels, under closure.

**Opposers behave with Duplicity**: In our short time working with GrayRobinson PA, and speaking with ICTV Brands, Inc. CEO Kelvin Claney (1-9-18) Applicant has seen a calculated pattern of dishonesty, a revolving door campaign that hinges its case on the specter of uncertainty, ambiguity, wild claims that cannot be supported. Bullying and threatening us "with dire financial ruin" and now (as of 1-03-18) ignoring our Motion requests. Are there consequences for that behavior? Will you elect to open our Disclosure discussion and uphold the high standards that make TM law transparent, accountable and fair for pro se Applicants like us?

Opposers have already elected to settle out of court, but talk is cheap. If and when they back-up their words with verifiable, documented facts, will the voracity of their claims manifest? We seek to bring pressure to bare on them, ***causing them to file a motion to dismiss their Notice of Opposition.*** Why? Their claims have sought to paint their Derma wand® item—as a direct duplicate (and in some claims) an exact carbon-copy of the **DermaCareWand™** device. This is key to understanding the depth of their unwavering deception. I have tried to show how each item *is as different by design, regulation and Indications of Use as possible.* So much so, that

a casual observer, having the gift of eyesight and average intelligence, seeing each laying on a table, side-by-side, will immediately see, understand and can differentiate clear and distinct dissimilarities. As for the combination words used, our inclusion of "Care" is a dominate indicator. HealthCARE, patient-CARE, physician-CARE, and safety of CARE...are indicators of what the **DermaCareWand™** actually is. "An Epidermal Lesion-Removal Triage System, for licensed dermatologists performing cryosurgery; workflow optimized, a physician extender in today's performance-based healthCARE ecosystem." Our device is patient-centric; it "cares."

Finally, anyone can claim their product "looks like a duck, quacks like a duck, even swims like a duck..." until it meets the DNA of a *Real Duck*. The ACR, and our Motion to "prove it" will put to rest the Opposers litany of lies.

In closing, please reply to us by email or phone (if you are able to open our Disclosure discussion). As before, Applicant lives in Lakewood, CO (Mountain time-zone). Applicant has requested in writing and over the phone, that the Opposer *"offers several workable times and dates for our phone-in teleconference schedule, with a start-time AFTER 12pm EST, on or before Saturday January 13, 2018."* As always, we are willing to meet them half-way, giving them their opportunity to prove their Derma wand® is an identical twin in every way they have claimed, to our **DermaCareWand™**.

We thank the parties for their cooperation.

Kind Regards,

Rory Krieger, CTO
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**CITED REFERENCES**

A1. FDA Requirements for Medical Devices
https://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/default.htm

A. ICTV Brands, Inc. television infomercial link
https://www.youtube.com/watch?v=uShYVAM1-pc
B. ISO 13485-2016, ISO 14971, ISO 9001
C. www.FDA.GOV
D. Dr. David J. Applebaum M.D. F.A.C.S Plastic Surgeon, Board Certified, paid by ICTV Brands, Inc. as physician pitch-man for Derma wand (Dw) item. See http://www.bocaratoncosmeticsurg.com/