To:	CVRx, Inc. (trademarkmpls@faegre.com)
Subject:	TRADEMARK APPLICATION NO. 77063672 - BAROREFLEX HYPERTENS - 75453-
Sent:	5/28/2008 1:57:06 PM
Sent As:	ECOM116@USPTO.GOV
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UNITED STATES PATENT AND TRADEMARK OFFICE

SERIAL NO: 77/063672

MARK: BAROREFLEX HYPERTENS

CORRESPONDENT ADDRESS:
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RESPOND TO THIS ACTION:
http://www.uspto.gov/teas/eTEASpageD.htm

GENERAL TRADEMARK INFORMATION:
http://www.uspto.gov/main/trademarks.htm

APPLICANT: CVRx, Inc.

CORRESPONDENT'S REFERENCE/DOCKET NO:
75453-

CORRESPONDENT E-MAIL ADDRESS:
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OFFICE ACTION

TO AVOID ABANDONMENT, THE OFFICE MUST RECEIVE A PROPER RESPONSE TO THIS OFFICE ACTION WITHIN 6 MONTHS OF THE ISSUE/MAILING DATE.

ISSUE/MAILING DATE: 5/28/2008

THIS IS A FINAL ACTION.

Upon further review of the application, the examining attorney inadvertently omitted the specimen refusal in the final action dated November 16, 2007. As such, it is necessary to issue the following subsequent final refusal regarding the specimen. Additionally, the examining attorney has carefully considered applicant's request for reconsideration regarding the 2(e)(1) refusal and 2(f) claim of acquired distinctiveness and found them unconvincing to overturn the refusal. Therefore, the 2(e)(1) final refusal is hereby maintained and continued.

This Office action supersedes any previous Office action issued in connection with this application.

STATEMENT OF THE CASE

Regarding the specimen, on April 16, 2007, the examining attorney issued an office action in which the applicant's specimen was refused because it did not sufficiently display the mark nor did it reference applicant's goods.

On October 16, 2007, applicant argued that the specimen was acceptable. The examining attorney carefully reviewed applicant's specimen argument and maintains that the specimen is unacceptable. Therefore, the specimen refusal is made **FINAL.**

SPECIMEN UNACCEPTABLE – FINAL ACTION

The specimen is not acceptable because it does not show the applied-for mark in use in commerce. An application based on Section 1(a) must include a specimen showing the applied-for mark in use in commerce for each class of goods. Trademark Act Sections 1 and 45, 15 U.S.C. §§1051, 1127; 37 C.F.R. §§2.34(a)(1)(iv), 2.56; TMEP §§904, 904.07(a). Here, the specimen is not acceptable as evidence of actual trademark use because it does not sufficiently display the mark nor does it reference applicant's goods, "medical devices, namely, implantable electrical stimulators, electrical leads, and computer hardware and software for the electrical stimulation of tissue or nerves used to manage or treat physiological disorders." Specifically, the mark is displayed on the front of the reference guide as "Rheos Baroreflex Hypertension Therapy System." The specimen does not make a commercial impression separate and apart from the other elements of the reference guide matter. Also, the guide consists of a table of contents and system description referencing a Rheos Implantable Pulse Generator Model, but does not provide instructions on applicant's goods. Thus, it fails to show proper use of the applied-for mark.

Applicant argues that "[t]he cover of the Guide clearly displays in large lettering: "Reference Guide" and "Rheos™ Baroreflex Hypertension Therapy™ System, where Rheos™ appears on a separate line, and "Reference Guide" appears alone on the right-hand margin of the cover. Applicant's CVRx trademark also appears in the upper left-hand corner of the cover. The most prominent wording on the cover is the mark Rheos™ and the mark Baroreflex Hypertension Therapy™. The Baroreflex Hypertension Therapy™ mark clearly stands alone as a separate mark."

As stated in the initial office action dated April 16, 2007, while a trademark mark does not have to be displayed in any particular size or degree of prominence, it must be used in a way that makes a commercial impression separate and apart from the other elements of the material upon which it is used, such that the designation will be recognized by prospective purchasers as a source identifier. *In re C.R. Anthony Co.*, 3 USPQ2d 1894 (TTAB 1987); *In re Post Properties, Inc.*, 227 USPQ 334 (TTAB 1985). The proposed mark must not blend so well with other matter on specimens that it is difficult or impossible to discern what the mark is. *In re McDonald's Corp.*, 229 USPQ 555 (TTAB 1985); *In re*

Royal Viking Line A/S, 216 USPQ 795 (TTAB 1982); *In re Republic of Austria Spanische Reitschule, supra; Ex parte National Geographic Society*, 83 USPQ 260 (Comm'r Pats. 1949). **Thus, the presence of the "TM" symbol is not dispositive of the issue of whether matter sought to be registered is used as a trademark.** *In re British Caledonian Airways Ltd.*, 218 USPQ 737 (TTAB 1983).

In this case, the cover of applicant's reference guide displays "Rheos Baroreflex Hypertension Therapy System" whereby each word appears on a separate line. Thus, "Baroreflex Hypertension Therapy" in not used in a way that makes a commercial impression separate and apart from the other elements, such that the designation would be recognized by prospective purchasers as a source identifier.

Applicant also argues that "[t]he third page of the specimen shows a drawing of the goods, namely, an implantable electrical stimulator, electrical leads, and computer hardware and software, sold as a unit. The Guide refers to the RHEOS implantable pulse generator and the RHEOS carotid sinus leads, both of which are parts of the BAROREFLEX HYPERTENSION THERAPY™ System which comprises all of the goods recited in the application."

Applicant's reference guide, specifically page three, provides a description of the CVRx Rheos System and its major components, as well as the Rheos Implantable Pulse Generator. However, it does not display the applied-for mark on this page or near these goods. Thus, "Baroreflex Hypertension Therapy" would not be recognized by prospective purchasers as a source identifier of applicant's goods based on this evidence. Furthermore, the information provided appears to be advertising and descriptive in nature rather than instructions for the goods.

Please note, material that functions merely to tell prospective purchasers about the goods, or to promote the sale of the goods, is unacceptable to show trademark use. Indeed, invoices, business cards, announcements, price lists, listings in trade directories, order forms, bills of lading, leaflets, brochures, publicity releases, advertising circulars and other printed advertising material, while normally acceptable for showing use in connection with services, generally are not acceptable specimens for showing trademark use in connection with goods. *See In re MediaShare Corp.*, 43 USPQ2d 1304, 1307 (TTAB 1997); *In re Schiapparelli Searle*, 26 USPQ2d 1520, 1522 (TTAB 1993); TMEP §§904.04(b)-(c).

Applicant states that the specimen "provides instructions for operating the goods and is packaged with the goods." However, if material inserted in a package with the goods is merely advertising material, then it is not acceptable as a specimen of use on or in connection with the goods. Material that is only advertising does not necessarily cease to be advertising because it is placed inside a package. TMEP §904.04(c)

Therefore, applicant must submit the following:

(1) A substitute specimen showing the mark in use in commerce for the goods specified in the application.

(2) The following statement, verified with an affidavit or signed declaration under 37 C.F.R. §2.20: "**The substitute specimen was in use in commerce at least as early as the filing date of the application.**" 37 C.F.R. §2.59(a); TMEP §904.05. If submitting a specimen requires an amendment to the dates of use, applicant must also verify the amended dates. 37 C.F.R. §2.71(c).

Examples of specimens for goods are tags, labels, instruction manuals, containers, photographs that show the mark on the goods or packaging, or displays associated with the goods at their point of sale. TMEP §§904.03 *et seq.*

If applicant cannot satisfy the above requirements, applicant may amend the Section 1(a) filing basis (use in commerce) to Section 1(b) (intent to use basis), for which no specimen is required. However, should applicant amend the basis to Section 1(b), registration cannot be granted until applicant later amends the application back to use in commerce by filing an acceptable allegation of use with a proper specimen. 15 U.S.C. §1051(c); 37 C.F.R. §§2.76, 2.88; TMEP Chapter 1100.

In order to amend to Section 1(b), applicant must submit the following statement, verified with an affidavit or a signed declaration under 37 C.F.R. §2.20: "**Applicant has had a bona fide intention to use the mark in commerce on or in connection with the goods or services listed in the application as of the filing date of the application.**" 15 U.S.C. §1051(b); 37 C.F.R. §§2.34(a)(2), 2.35(b)(1); TMEP §806.03(c).

Pending a proper response, registration is refused because the specimen does not show the applied-for mark in use in commerce as a trademark. 15 U.S.C. §§1051, 1127; 37 C.F.R. §§2.34(a)(1)(iv), 2.56; TMEP §§904, 904.07(a).

2(E)(1) REQUEST FOR RECONSIDERATION

The examining attorney has carefully reviewed applicant's 2(e)(1) request for reconsideration and found it unconvincing. Therefore, the 2(e)(1) refusal is continued and maintained. As previously stated in the final action dated November 16, 2007, terms that describe the function or purpose of a product may be merely descriptive or generic under 15 U.S.C. §1051(e)(1). *In re Gould Paper Corp.*, 834 F.2d 1017, 5 USPQ2d 1110 (Fed. Cir. 1987) (SCREENWIPE held generic for an anti-static cloth used for cleaning computer and television screens); *In re Central Sprinkler Co.*, 49 USPQ2d 1194 (TTAB 1998) (ATTIC generic for sprinklers installed primarily in attics); *In re Reckitt & Colman, North America Inc.*, 18 USPQ2d 1389 (TTAB 1991) (PERMA PRESS generic for soil and stain removers for use on permanent press products); *In re Wallyball, Inc.*, 222 USPQ 87 (TTAB 1984) (WALLYBALL held descriptive of sports clothing and game equipment); *In re National Presto Industries, Inc.*, 197 USPQ 188 (TTAB 1977) (BURGER held merely descriptive of cooking utensils); *In re Orleans Wines, Ltd.*, 196 USPQ 516 (TTAB 1977) (BREADSPRED held merely descriptive of jams and jellies).

Furthermore, the fact that an applicant may be the first and only user of a merely descriptive designation is not dispositive on the issue of descriptiveness where, as here, the evidence shows that the word or term is merely descriptive. *See In re Sun Microsystems, Inc.*, 59 USPQ2d 1084, 1087 (TTAB 2001); *In re Acuson*, 225 USPQ 790, 792 (TTAB 1985); TMEP §1209.03(c).

Applicant's mark merely describes both the function and purpose of its goods. That is, applicant's goods, namely, "implantable electrical stimulators, electrical leads, and computer hardware and software sold as a unit for the electrical stimulation of tissue or nerves used to manage or treat physiological disorders," are medical devices whereby their function and purpose is to conduct BAROREFLEX HYPERTENSION THERAPY through the electrical stimulation of tissue or nerves used to manage and treat physiological disorders. Please see additional evidence attached and at the bottom of this office action.

2(F) CLAIM – ACQUIRED DISTINCTIVENESS

The refusal of registration under Trademark Act Section 2(e)(1) is continued, notwithstanding applicant's claim of acquired distinctiveness under Section 2(f). Trademark Act Sections 2(e)(1) and 2(f), 15 U.S.C. §1052(e)(1), (f); TMEP §1209.02.

Registration was refused because the applied-for mark is merely descriptive of applicant's goods. Trademark Act Section 2(e)(1), 15 U.S.C. §1052(e)(1); *see* TMEP §§1209.01(b), 1209.03 *et seq.*

Applicant's claim of acquired distinctiveness is insufficient to overcome the refusal. Trademark Act Section 2(f), 15 U.S.C. §1052(f); *see In re Andes Candies, Inc.*, 478 F.2d 1264, 1267, 178 USPQ 156, 158 (C.C.P.A. 1973); *In re Kalmback Publ'g Co.*, 14 USPQ2d 1490, 1492 (TTAB 1989); *In re MetPath, Inc.*, 1 USPQ2d 1750, 1751-52 (TTAB 1986); TMEP §§1212, 1212.01.

Applicant has the burden of proving acquired distinctiveness of its mark. TMEP §1212.01; *see Yamaha Int'l Corp. v. Hoshino Gakki Co.*, 840 F.2d 1572, 1578-79, 6 USPQ2d 1001, 1006 (Fed. Cir. 1988); *In re Meyer & Wenthe, Inc.*, 267 F.2d 945, 949, 122 USPQ 372, 374-75 (C.C.P.A. 1959). To establish acquired distinctiveness, applicant must show that, in the minds of the public, the primary significance of an applied-for mark is to identify the source of the product or service rather than to identify the product or service itself. *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 851 n.11, 214 USPQ 1, 4 n.11 (1982); TMEP §1212.03. Applicant has not met its burden in this case.

The amount and character of evidence needed to establish acquired distinctiveness depends on the facts of each case and particularly on the nature of the mark sought to be registered. *Roux Labs., Inc. v. Clairol Inc.*, 427 F.2d 823, 829, 166 USPQ 34, 39 (C.C.P.A. 1970); *see In re Hehr Mfg. Co.*, 279 F.2d 526, 126 USPQ 381 (C.C.P.A. 1960); TMEP §1212.05(a).

More evidence is required where a mark is so highly descriptive that purchasers seeing the matter in relation to the named goods would be less likely to believe that it indicates source in any one party. *See, e.g., In re Bongrain Int'l Corp.*, 894 F.2d 1316, 13 USPQ2d 1727 (Fed. Cir. 1990); *In re Seaman & Assocs., Inc.*, 1 USPQ2d 1657 (TTAB 1986).

However, no amount of purported proof that a generic term has acquired secondary meaning can transform that term into a registrable trademark. Such a designation cannot become a trademark under any circumstances. *See In re Bongrain*, 894 F.2d at 1317 n.4, 13 USPQ2d at 1728 n.4; *H. Marvin Ginn Corp. v. Int'l Ass'n of Fire Chiefs, Inc.*, 782 F.2d 987, 989, 228 USPQ 528, 530 (Fed. Cir. 1986); TMEP §1212.02(i).

In this case, applicant asserts that "the mark BAROREFLEX HYPERTENSION THERAPY has become distinctive of Applicant's goods as a result of substantially exclusive and continuous use of the mark in interstate commerce in connection with Applicant's goods since at least as early as July 31, 2003." Based on applicant's evidence of acquired distinctiveness, namely, the specimen submitted with the original application, applicant's claim of acquired distinctiveness is insufficient to overcome the refusal.

PROPER RESPONSE TO FINAL OFFICE ACTION

If applicant does not respond within six months of the mailing date of this final Office action, the application will be abandoned. 15 U.S.C. §1062(b); 37 C.F.R. §2.65(a). Applicant may respond to this final Office action by:

(1) Submitting a response that fully satisfies all outstanding requirements, if feasible; and/or

(2) Filing an appeal to the Trademark Trial and Appeal Board, with an appeal fee of $100 per class.

37 C.F.R. §§2.6(a)(18), 2.64(a); TBMP ch. 1200; TMEP §714.04.

In certain rare circumstances, a petition to the Director may be filed pursuant to 37 C.F.R. §2.63(b)(2) to review a final Office action that is limited to procedural issues. 37 C.F.R. §2.64(a); TMEP §714.04; *see* 37 C.F.R. §2.146(b); TBMP §1201.05; TMEP §1704 (explaining petitionable matters).. The petition fee is $100. 37 C.F.R. §2.6(a)(15).

/tfrazier/
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RESPOND TO THIS ACTION: If there are any questions about the Office action, please contact the assigned examining attorney. A response to this Office action should be filed using the form available at http://www.uspto.gov/teas/eTEASpageD.htm. If notification of this Office action was received via e-mail, no response using this form may be filed for 72 hours after receipt of the notification. **Do not attempt to respond by e-mail as the USPTO does not accept e-mailed responses.**

If responding by paper mail, please include the following information: the application serial number, the mark, the filing date and the name, title/position, telephone number and e-mail address of the person signing the response. Please use the following address: Commissioner for Trademarks, P.O. Box 1451, Alexandria, VA 22313-1451.

STATUS CHECK: Check the status of the application at least once every six months from the initial filing date using the USPTO Trademark Applications and Registrations Retrieval (TARR) online system at http://tarr.uspto.gov. When conducting an online status check, print and maintain a copy of the complete TARR screen. If the status of your application has not changed for more than six months, please contact the assigned examining attorney.

Abstract

Am J Hypertens (2005) 18, 213A–213A; doi:10.1016/j.amjhyper.2005.03.584

P-567: Baroreflex hypertension therapy for resistant hypertension

D.A. Sica1, R.S. Kieval1, R.C. Martin1 and E.D. Irwin1

1Virginia Commonwealth University; CVRx, Inc., Maple Grove, MN; North Memorial Medical Center, Robinsdale, MN.

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Abstract

At least 10% of all patients with hypertension are resistant to existing therapies. These patients are at increased risk of cardiovascular events and progressive kidney disease. In the face of uncontrolled hypertension, alternative therapies are needed. A device based Baroreflex Hypertension Therapy (BHT) is being developed to treat these patients. This therapy works by electrically activating the carotid baroreflex. The device generates signals that are centrally interpreted as a rise in blood pressure. The brain responds by modulating autonomic nervous activity and thereby lowering blood pressure. Initial study results suggest that electrical activation of the carotid baroreflex results in sustained, dose dependent reduction in blood pressure. The system includes: implantable pulse generator, carotid sinus leads, and programmer. The leads have electrical contacts that are positioned on the carotid sinus and conduct activation energy from the pulse generator to the left and right carotid sinus. The programmer provides the ability to non-invasively program the pulse generator. This new therapy has been studied in canines and is being evaluated in clinical trials. Early data suggests blood pressure can be reduced with this device in patients with otherwise resistant hypertension as defined by a blood pressure of 160 mm-Hg systolic while receiving three or more drugs (with one being a diuretic) at maximal doses for at least two months.

From Medscape Cardiology

Chronic Treatment of Resistant Hypertension With the Rheos Baroreflex Hypertension Therapy System

Posted 06/12/2007

Linda Brookes, MSc
Author Information

The latest combined data from European and US phase 2 clinical trials with an implantable device being developed to treat patients with drug-refractory hypertension were reported at the Innovation in Intervention: i2 Summit 2007, held as a subset of, and in conjunction with, the 2007 American College of Cardiology (ACC) meeting and cosponsored by the Society for Cardiovascular Angiography and Interventions.[1] Presenter Peter W. de Leeuw, MD, PhD (University Hospital Maastricht, The Netherlands) said that the investigators are pleased with the early clinical results to date and are optimistic about this novel treatment approach.

Refractory or resistant hypertension is usually defined as blood pressure that remains above goal (140/90 mm Hg in most patients or 130/80 mm Hg in those with diabetes or renal disease or systolic blood pressure (SBP) > 160 mm Hg in patients with isolated systolic hypertension) despite adherence to an appropriate 3-drug regimen including a diuretic.[2,3] Estimates of the prevalence of truly resistant hypertension vary from 5%[4] to 40%[5] of the treated hypertensive population. Without further options, these patients are at high risk for myocardial infarction (MI), stroke, and heart and kidney failure.

The Device

The Device

The Rheos Baroreflex Hypertension Therapy (BHT) system (CVRx; Minneapolis, Minnesota) provides a "physiologic rationale" method to reduce blood pressure. The system's proprietary technology uses the body's own natural blood pressure regulation system (baroreflex) to control blood pressure. The Rheos BHT system includes:

- A small pulse generator that is implanted under the collarbone;
- Two thin lead wires that are implanted at the left and right carotid arteries and which connect to the pulse generator; and
- The Rheos Programmer system, an external device used by physicians to noninvasively regulate the activation energy from the generator to the lead wires.

The system electronically activates the baroreflex, which sends signals to the brain that are interpreted by the brain as suggesting a blood pressure increase. The brain then acts to lower blood pressure by signaling various neural control systems in the body to reduce blood pressure, including the blood vessels, heart, and kidneys.

Study Parameters and Results

Prof de Leeuw presented an analysis of combined data from 27 patients (17 European and 10 US) participating in the US Rheos Feasibility Trial and the European Device Based Therapy of Hypertension Trial (DEBuT-HT). These data were presented separately in 2006.[3,7] [See ESH 2006 and AHA 2006 Medscape reports.] All of the patients (14 men and 13 women, mean age 52 years) had stage 2 hypertension (≥ 160 mm Hg) despite taking 3 or more antihypertensive medications, including a diuretic.

The Rheos BHT was surgically implanted in these patients and was then activated 1 month later. All subjects remained on antihypertensive therapy during the study. One patient developed an infection before 3 months and was excluded from the analysis. After 6 months of active Rheos BHT treatment, SBP in the remaining patients was significantly reduced by an average of 21 mm Hg (166 vs 187 mm Hg, $P = .007$) and diastolic blood pressure (DBP) was significantly reduced by an average of 16 mm Hg (96 vs 112 mm Hg, $P = .0004$) (Table). Heart rate was also reduced significantly by 9 bpm (72 vs 81 bpm, $P = .013$). The Rheos BHT system continues to be effective in controlling blood pressure even after 1 year, Prof de Leeuw reported.

To date (March 1, 2007), 49 patients have been implanted with the Rheos BHT system worldwide, providing 822 patient-months of follow-up. The implants have been well tolerated, with no unexpected serious adverse events. There have been no reports of postural hypertension associated with the device, there is no evidence of stenosis of the carotid artery out to 1 year, and there have been no lead or pulse generator failures. Twelve system- or procedure-related adverse events have been reported in 10 subjects. Most of these were resolved and did not lead to the patient's exclusion from the study.

Further Studies

Prof de Leeuw believes that the Rheos BHT treatment approach could offer a new option for patients with drug-resistant hypertension, saying that "It may prevent progression to more serious illnesses and death." A larger study has begun to further assess long-term benefit of the system. In October 2006, CVRx received conditional investigational device exemption (IDE) approval from the Food and Drug Administration (FDA) to begin a US pivotal clinical trial that is evaluating the safety and effectiveness of Rheos BHT in a much larger number of patients.

The Rheos Pivotal Trial is a prospective, blinded, randomized clinical trial that will be conducted in 300 patients at up to 50 medical sites. To be enrolled in the trial, patients need to be resistant to treatment with 3 or more antihypertension agents, including a diuretic, and their SBP must be ≥ 160 mm Hg. Prior to randomization, patients will have their device turned off for 1 month following the implant. After 1 month, patients will be randomized at a 2:1 ratio to Rheos BHT "on" or "off" for the first 6 months. After 6 months, all patients will receive active therapy. At the end of 12 months, patients in the "on" group who are considered to be responders – defined as a ≥ 10 mm Hg reduction in office cuff SBP – will be assessed for sustained response. Patients will then be followed on a quarterly basis until study closure. Results from this study are intended to support the Pre-Market Approval (PMA) application for the Rheos BHT system to the FDA.

Findings from 2 preclinical studies that evaluated the Rheos BHT system in canine subjects with heart failure were also presented at the ACC meeting. In both studies, Rheos BHT was found to improve left ventricular function [3,5]

References

Medscape Cardiology. 2007; ©2007 Medscape

http://209.85.215.104/search?q=cache:v-pdQ-oH5gEJ:medgadget.com/archives/2006/11/positive_result.html+%22baroreflex+hypertension%22&hl=en&ct=clnk&cd=4&gl=us 05/21/2008 05:45:47 PM

medGadget
internet journal of emerging medical technologies

Thursday, November 16, 2006

Positive Results from Trial of Rheos Baroreflex Hypertension Therapy

Filed under: Cardiology , Medicine , Vascular Surgery

More interesting news coming our way from the American Heart Association 2006 Scientific Sessions in Chicago. Research done by the University of Rochester Medical Center shows that Rheos™ **Baroreflex Hypertension** Therapy™ System, a product of CVRx®, Inc., shows promise for drug resistant hypertensives. As we have previously reported, the investigational device by a Minneapolis, MN company functions through activation of carotid baroreceptors, and is implanted surgically.

Here's what University of Rochester says about its research:

> The trial is designed to assess device safety and efficacy in patients with systolic blood pressure of 160 mmHg or greater, despite being on at least three anti-hypertension medications, including one diuretic. The presentation reported on the first 10 U.S. patients enrolled in the trial. After one month of surgical recovery, baseline blood pressure was assessed and the device was activated. Three months of active Rheos therapy reduced systolic blood pressure by an average of 22 mmHg (180 mmHg vs. 158 mmHg) and diastolic blood pressure by an average of 18 mmHg (105 mmHg vs. 87 mmHg), using office cuff measurements. The implants were well tolerated and there were no unanticipated serious adverse events related to the system or procedure.

The press release...

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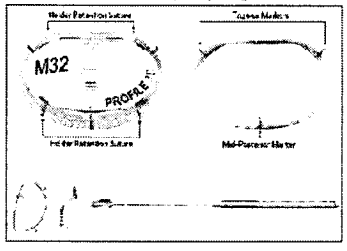

Medtronic has announced the U.S. launch of its Profile 3D™ Annuloplasty Ring for mitral valve repairs. The company touts the three-dimensional annuloplasty ring configuration as a design that can potentially offer more "natural mitral geometry" for "natural valve dynamics" and the

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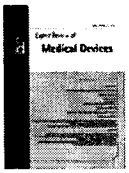

Rheos® Baroreflex Hypertension Therapy™ System to treat resistant hypertension

Authors: Scheffers, Ingrid JM[1]; Kroon, Abraham A; Tordoir, Jan HM; de Leeuw, Peter W

Source: Expert Review of Medical Devices, Volume 5, Number 1, January 2008 , pp. 33-39(7)

Publisher: Expert Reviews

Abstract:

Resistant hypertension has a high prevalence and is associated with high morbidity and mortality. The Rheos® Baroreflex Hypertension Therapy™ System is an implantable device that offers a completely new approach to treating patients with resistant hypertension by electrically activating the carotid baroreflex. Preliminary results from current feasibility clinical trials have shown sustained decreases in blood pressure after 1 year. The pivotal trial for US FDA approval and market release is currently ongoing. This article profiles the Rheos System and evaluates the treatment of resistant hypertension in general.

Keywords: baroreceptors; carotid sinus; drug resistant; hypertension; surgery

Document Type: Research article

DOI: 10.1586/17434440.5.1.33

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Am J Physiol Regul Integr Comp Physiol 256: R1044-R1049, 1989;
0363-6119/89 $5.00

AJP - Regulatory, Integrative and Comparative Physiology, Vol 256, Issue 5 1044-R1049, Copyright © 1989 by American Physiological Society

ARTICLES

ANP and sodium excretion during acute baroreflex hypertension in conscious dogs

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The influence of an acute baroreflex hypertension elicited by common carotid occlusion (CCO) on plasma atrial natriuretic peptide (ANP) and renal sodium excretion was investigated in chronically instrumented, conscious foxhounds receiving a normal-sodium diet. CCO (n = 6) significantly increased mean arterial pressure (from 102 +/- 5 to 144 +/- 3 mmHg; P less than 0.01) and sodium excretion (from 82 +/- 10 to 133 +/- 9 mumol/min; P less than 0.05). No changes in plasma ANP and right atrial pressure were observed during the acute hypertension. In contrast, an acute 20% volume expansion (n = 7) corresponding to 1.8% of body weight raised right atrial pressure (from 1.3 +/- 1.2 to 5.8 +/- 1.2 cmH2O; P less than 0.01) and induced a sustained elevation of plasma ANP (from 39 +/- 8 to 67 +/- 16 pg/ml; P less than 0.05). The natriuresis in response to CCO was eliminated when renal perfusion pressure was regulated at the control level by a renal arterial cuff (n = 4); under these conditions, sodium excretion even tended to decrease during CCO (from 81 +/- 17 to 46 +/- 13 mumol/min; P less than 0.05). In conclusion, an increase in renal perfusion pressure and not an elevated ANP level is important in mediating the natriuresis during CCO in conscious dogs. These results imply that changes in plasma ANP are not essential for the induction and maintenance of a pressure natriuresis.

To:	CVRx, Inc. (**trademarkmpls@faegre.com**)
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Sent As:	ECOM116@USPTO.GOV
Attachments:	

IMPORTANT NOTICE
USPTO OFFICE ACTION HAS ISSUED ON 5/28/2008 FOR APPLICATION SERIAL NO. 77063672

Please follow the instructions below to continue the prosecution of your application:

VIEW OFFICE ACTION: Click on this link **http://tmportal.uspto.gov/external/portal/tow?DDA=Y&serial_number=77063672&doc_type=OOA&mail_date=20080528** (or copy and paste this URL into the address field of your browser), or visit **http://tmportal.uspto.gov/external/portal/tow** and enter the application serial number to **access** the Office action.

PLEASE NOTE: The Office action may not be immediately available but will be viewable within 24 hours of this notification.

RESPONSE MAY BE REQUIRED: You should carefully review the Office action to determine (1) if a response is required; (2) how to respond; and (3) the applicable **response time period**. Your response deadline will be calculated from **5/28/2008**.

Do NOT hit "Reply" to this e-mail notification, or otherwise attempt to e-mail your response, as the USPTO does NOT accept e-mailed responses. Instead, the USPTO recommends that you respond online using the Trademark Electronic Application System response form at http://www.uspto.gov/teas/eTEASpageD.htm.

HELP: For *technical* assistance in accessing the Office action, please e-mail **TDR@uspto.gov**. Please contact the assigned examining attorney with questions about the Office action.

WARNING

1. The USPTO will NOT send a separate e-mail with the Office action attached.

2. Failure to file any required response by the applicable deadline will result in the ABANDONMENT of your application.