

August 19, 2008

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VIA FEDEX

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Citizen Petition
Deny Patent Term Extension of U.S. Patent No. 5,451,233 based on
approval of XIENCE™ V EECSS
Our Reference No. 021770-000500US

CITIZEN PETITION

A. Specific Regulatory Action Requested

On behalf of AngioScore, Inc. ("AngioScore"), the following citizen petition is being submitted pursuant to Section 4(d) of the Administrative Procedure Act, 5 U.S.C. § 553(e), Section 156 of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), including 35 U.S.C. § 156(a), 156(a)(5)(A), 156(d)(1) and 37 C.F.R. § 1.720(f) and regulations established by the Food and Drug Administration ("FDA") governing due diligence petitions, codified at 21 C.F.R. § 10.30 to request that the FDA deny the Patent Term Extension of U.S. Patent 5,451,233 requested by Abbott Cardiovascular Systems Inc. ("ACS") under 35 U.S.C. § 156 on the basis of the Agency's July 2, 2008 approval of the XIENCE™ V Everolimus Eluting Coronary Stent System ("XIENCE V EECSS").

On July 30, 2008, the U.S. Patent and Trademark Office ("USPTO") requested FDA assistance in confirming that the XIENCE V EECSS was subject to a regulatory review period (USPTO letter attached as Appendix 1). For the reasons summarized below and set forth in greater detail in Section B of this petition, FDA should deny any period of extension requested by ACS for the 5,451,233 patent on the basis of the XIENCE V EECSS approval.

A Patent Term Extension ("PTE") for the '233 patent should be denied because:

1. To the extent eligibility for a PTE is sought based on the medical device portion of the combination product (the RX catheter portion of which is the only part claimed by the '233 patent), it is time barred under 35 U.S.C. §§ 156(a)(5)(A), 156(d)(1) and 37 C.F.R. § 1.720(f), as the identified medical devices were previously approved in 2003 and 2004, so this is not the "first permitted commercial marketing or use of the product" and the 60 day period

for seeking a PTE based on approval of those medical devices has long since expired;

2. To the extent eligibility for a PTE is sought based on the drug portion of the combination product (e.g., the drug eluting stent) or the combination product itself, the Application should be denied as the '233 patent does not claim either the drug product or the combination, so neither can form the basis of an extension under 35 U.S.C. § 156(a);
3. Should a PTE be granted based on the combination of the medical device and the drug, its grant would unreasonably extend the temporal patent monopoly and/or improperly expand the scope of patent coverage to a subject matter never claimed, frustrating the policies behind 35 U.S.C. § 154 and the Hatch-Waxman Act.

B. Statement of Factual and Legal Grounds Supporting Requested Action

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act ("the Hatch-Waxman Act," P.L. 98-417). The patent term restoration portion of the Hatch-Waxman Act was designed to create new incentives for research and development of products subject to government approval. In particular, owners of patents covering certain drugs, medical devices and food additives may restore to the terms of those patents time lost while awaiting pre-market government regulatory approval. The requirements for obtaining patent term extension ("PTE") are codified in 35 U.S.C. § 156.

1. The '233 Patent

The '233 patent is entitled "Angioplasty Apparatus Facilitating Rapid Exchanges," is owned by Paul G. Yock and has been exclusively licensed to Abbott Cardiovascular Systems, Inc., a division of Abbott Laboratories. The '233 patent was filed on March 9, 1994, issued on September 19, 1995, and is currently set to expire on October 29, 2008.

The '233 patent discloses an angioplasty catheter that may be rapidly loaded over and unloaded from a guidewire during an angioplasty procedure. Angioplasty is a minimally invasive medical procedure in which a balloon tipped catheter is introduced into the vasculature and advanced through the blood vessels to the site of a narrowed or totally occluded blood vessel. The balloon tipped catheter is positioned into the narrowed region of the vessel and then inflated. Expansion of the balloon mechanically widens the obstructed region thereby restoring blood flow through the affected vessel. In conventional, over-the-wire (OTW) angioplasty, the balloon catheter is loaded over a guidewire. Because the guidewire must traverse from the stenotic lesion in the patient through the entire length of the catheter shaft which may be partially in the patient's body and partially exposed outside the body, guidewires can be extremely long, e.g., 300 cm or more. Handling the guidewire becomes cumbersome and it is easy for the long guidewire to fall off the operating table onto the floor and become contaminated. Often two people are required during over-the-wire procedures just to handle the guidewire to keep it within the sterile field.

The '233 patent addresses this challenge by shortening the guidewire lumen in the angioplasty catheter. Instead of extending the entire length of the catheter, from distal tip to proximal end, the guidewire lumen extends from the distal tip of the catheter to a proximal exit port that is close to the catheter tip. The proximal exit port is therefore closer to the distal tip of the catheter than to the proximal end of the catheter so the guidewire only traverses a length of about 10-30 cm in the catheter, as opposed to its entire length in OTW systems. This allows a shorter guidewire to be used during interventional procedures and a single physician can manipulate both the catheter and the guidewire, hence this configuration is termed "rapid exchange," or "RX."

While the '233 patent discloses using RX technology for angioplasty, it does not disclose, teach or even suggest using RX technology to deliver stents or drug coated stents. In fact, the term "stent" never appears in the '233 patent specification and no drugs are identified in the '233 patent. Under 35 U.S.C. § 156(a), a patent must "claim" a product or a method of using or manufacturing a product in order to be eligible for patent term extension. (*In re Alcon Laboratories, Inc.*, 13 U.S.P.Q.2d (BNA) 1115, 1118 (Commr. Pat. 1989).) Because the '233 patent does not claim a rapid exchange delivery of drug eluting stents, it should not be eligible for patent term extension on the basis of the Xience V EECSS approval.

2. The FDA Approved Product

The XIENCE V EECSS was approved by the FDA on July 2, 2008. The XIENCE V EECSS product is a combination product that has a device component and a drug component. In ACS' Instructions for Use for this product, it is described as "a device/drug combination product consisting of either the MULTI-LINK VISION Coronary Stent System or the MULTI-LINK MINI VISION Coronary Stent System coated with a formulation containing everolimus, the active ingredient, embedded in a non-erodible polymer." (Instructions for Use, Product Description, Section 1.0.) The device component has been identified by ACS as either the MULTI-LINK VISION[®] Coronary Stent System or the MULTI-LINK MINI VISION[®] Coronary Stent System. The drug portion includes a drug eluting stent coated with the active ingredient everolimus. Neither the drug eluting stent nor the drug itself is covered by the '233 patent. Only the RX catheter portion of the device component of the XIENCE V EECSS combination product (the MULTI-LINK VISION Coronary Stent System and the MULTI-LINK MINI VISION Coronary Stent System) is covered by the '233 patent. While the combination was recently approved by the FDA, the MULTI-LINK VISION Coronary Stent System was previously approved by the FDA on July 16, 2003 and the MULTI-LINK MINI VISION Coronary Stent System was previously approved by the FDA on September 10, 2004.

The identical stent systems (including the RX catheter components) identified by ACS as the device portion of the approved combination product were previously approved by the FDA. The MULTI-LINK VISION Coronary Stent System was approved by the FDA on July 16, 2003 (PMA P020047). The MULTI-LINK MINI VISION Coronary Stent System was approved by the FDA on September 10, 2004 (PMA P020047 Supp. No. S003). Only the drug/polymer portion of this combination product and the combination itself are new, not the stent system that contains the RX technology disclosed in the '233 patent. Neither the drug/polymer portion nor the drug itself is covered by the '233 patent.

3. ACS' Application for PTE

On July 25, 2008, ACS filed an Application for Patent Term Extension Pursuant to 35 U.S.C. § 156 ("Application") with the USPTO. This request is predicated on the July 2, 2008 PMA approval of the XIENCE V EECSS (PMA No. 070015). ACS seeks a patent term extension of the '233 patent by 937 days. Approval of ACS' Application would extend the life of the '233 patent until May 24, 2011.

The '233 patent claims cover only the RX catheter portion of the approved combination product. They do not cover either the drug component or the entire combination. As set forth above, the RX catheter portions of the combination product on which this Application is predicated (as part of the MULTI-LINK VISION Coronary Stent System and the MULTI-LINK MINI VISION Coronary Stent System) were first approved by the FDA in 2003 and 2004. Because the exact device portion of the combination product was previously approved, ACS cannot demonstrate under 35 U.S.C. § 156(a)(5)(A) that its Application is based on the "first permitted commercial marketing or use"¹ of the MULTI-LINK VISION Coronary Stent System or the MULTI-LINK MINI VISION Coronary Stent System.

No application for PTE of the '233 patent was filed within 60 days of the first FDA approval of either the MULTI-LINK VISION Coronary Stent System or the MULTI-LINK MINI VISION Coronary Stent System. Accordingly, ACS missed its opportunity to seek a PTE based on approval of either the MULTI-LINK VISION Coronary Stent System or the MULTI-LINK MINI VISION Coronary Stent System and cannot recapture it now, through the guise of a combination product.

Indeed, this case is analogous to *In re Alcon Laboratories, Inc.*, 13 U.S.P.Q.2d (BNA) 1115 (Comm. Pat. 1989), in which a PTE was not granted.² In *Alcon*, the product upon which a PTE was sought was a combination drug product (Tobradex) containing tobramycin (A) and dexamethasone (B). Both A and B were previously approved by the FDA, but the combination product (A+B) was not. The FDA found approval of the combination product did not warrant a PTE. It reasoned that either A, B or the combination could be a "product" under 35 U.S.C. §156(a). But to be eligible for a patent term extension, the "product" also must be covered by at least one patent claim in the patent for which a PTE was sought. In *Alcon*, only A was claimed by the patent; neither B nor A+B was claimed by the patent. As such, only A could provide

¹ This situation is entirely different from that in *Cardiac Pacemakers, Inc. et al. v. St. Jude Medical, Inc., et al.*, 381 F.3d 1371 (Fed. Cir. 2004), where the particular approved medical device had not been previously approved by the FDA, even though different medical devices also covered by the patent claims had been approved. Even though 35 U.S.C. § 156(a)(5)(A) may not require a PTE application to be filed within 60 days of the first approved medical device product that falls within the claims of the patent, it does not permit seeking a PTE based on a second approval of the same medical device as is the case here.

² One factual difference between *Alcon* and this case is that, in *Alcon*, the applicant for the PTE advised the USPTO that the components of the combination product had been previously approved, consistent with its duty of candor under 37 C.F.R. § 1.765. In contrast, here ACS neglected to inform the USPTO that the medical device component of its combination product was previously approved. This fact further supports denying ACS' Application.

eligibility for an extension, but because it was previously approved by the FDA, a PTE was denied.

Application of the *Alcon* decision here similarly warrants denial of ACS' Application. Here, the "product" under 35 U.S.C. § 156(a) could be the device components (A), the drug component (B) or the combination (A+B). The device components (A), including the RX catheter portions which are covered by the '233 patent, were previously approved by the FDA so do not make the '233 patent eligible for an extension under 35 U.S.C. § 156(a)(5)(A). And, because neither the drug component (B) nor the combination (A+B) is claimed by the '233 patent, neither makes the '233 patent eligible for an extension under 35 U.S.C. § 156(a). As none of A, B or A+B provide eligibility for a PTE for the '233 patent, ACS' Application should be denied.

Thus, neither component nor the combination product makes the '233 patent eligible for extension. AngioScore, therefore, respectfully requests that ACS' Application be denied.

Additionally, AngioScore respectfully requests that any requests for interim patent term extension under 35 U.S.C § 156(e)(2) also be denied. Under this provision, if the term of a patent for which an application has been submitted under 35 U.S.C. § (d)(1) would expire before a certificate of extension is issued or denied under paragraph (1) respecting the application, the Director shall extend, until such determination is made, the term of the patent for periods of up to one year if he determines that the patent is eligible for extension. Because the '233 patent is not eligible for patent term extension as discussed previously, any requests by Abbott for an interim extension should be denied.³

4. Granting ACS' Application Would Improperly Extend or Expand the '233 Patent Coverage

Granting ACS' Application, notwithstanding the ineligibility of the '233 patent for a PTE on the basis of the Xience approval, would frustrate the policies behind both the establishment of patent terms as reflected in 35 U.S.C. § 154 and the policies reflected in the Hatch-Waxman Act regarding patent term extensions. Specifically, the '233 patent monopoly would be unduly extended contrary to 35 U.S.C. § 154(a)(2) for a patent for which ACS has already enjoyed full benefit.

Title 35, Section 154(a)(2) expressly defines the term of a patent. Only pursuant to narrow exceptions can the term be extended. Title 35, Section 156 (the patent term restoration portion of the Hatch-Waxman Act), is one such exception. This exception was designed to create new incentives for research and development of products subject to government approval,

³ Additionally, under 35 U.S.C. § 156(e)(1) a determination that a patent is eligible from extension may be made by the Director solely on the basis of the representations contained in the application for the extension. Abbott's failure to disclose material information related to previous FDA approvals of the MULTI-LINK VISION Coronary Stent System or the MULTI-LINK MINI VISION Coronary Stent System renders the application for PTE incomplete; accordingly, no interim extension would be properly requested until ACS' Application is made complete.

in particular, extending the patent monopoly due to time lost while waiting for pre-market government regulatory approval. In this case, however, ACS or its predecessors have already reaped the benefit of the full '233 patent term, making the policy behind an extension inapplicable here.

As discussed above, the '233 patent is directed to balloon catheters having rapid exchange (RX) configurations. In addition to the particular medical devices identified in ACS' combination product which were approved years ago, many other similar stents and balloon catheters have been previously approved by the FDA. (See Appendix 2, attached.) Rapid exchange angioplasty catheters have been commercialized by Abbott or its predecessor companies (e.g., Advanced Cardiovascular Systems and Guidant Corp.) since at least 1990, years before the '233 patent even issued. For example, Advanced Cardiovascular Systems received pre-market approval for the ACS RX Alpha Coronary Dilatation Catheter on April 20, 1990 under PMA No. P810046, Supplement No. S067. Advanced Cardiovascular Systems received numerous other PMA approvals for other RX angioplasty catheters after submitting PMA Supplements for changes in design, components or specifications. Some of these RX product approvals are summarized in Appendix 2, attached. Advanced Cardiovascular Systems (now Abbott) has enjoyed the benefits of the '233 patent throughout its entire (unextended) term. It lost no portion of its patent term while awaiting FDA approval on any of these products. In fact, ACS successfully asserted the '233 patent against Medtronic in 2001, obtaining millions of dollars in damages and an injunction (*Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc.*, 265 F.3d 1294 (Fed. Cir. 2001)).

Additionally, RX balloon catheters have also been used in stent delivery systems for a number of years. Abbott and its predecessor companies (Advanced Cardiovascular Systems and Guidant) have a long history of commercializing RX stent delivery systems. Some of the FDA approved RX stent delivery systems are summarized in Appendix 3, attached.

Currently, well over one million interventional catheter procedures (angioplasty and/or stenting) are performed worldwide and Abbott is a significant supplier of the catheters used during such procedures.

The '233 patent issued nearly thirteen years ago, well after the first RX technology was first commercialized. Abbott has received the full benefit of patent protection during the entire term of the '233 patent to date. It has not lost any benefit while awaiting pre-market government regulatory approval. Thus, the purposes behind the patent term restoration act would not be advanced by extension of the term of the '233 patent. Instead, an extension under these circumstances would unfairly provide ACS a benefit far beyond the policy behind the Hatch-Waxman Act – and contrary to the patent term established by 35 U.S.C. § 154(a). Accordingly, an extension of this patent at this late date (just months before its expiration), particularly when a component of the approved device covered by this patent was long ago approved, would frustrate the purposes of 35 U.S.C. § 154, 156 and the Hatch-Waxman Act.

C. Environmental Impact

The action requested is subject to a categorical exclusion from environmental assessment under 21 C.F.R. § 25.30(h).

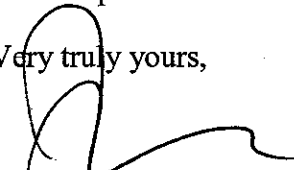
D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), we will provide data concerning the economic impact of the action requested should such information be requested by the FDA.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Very truly yours,



James M. Heslin,
on behalf of AngioScore, Inc.
5055 Brandin Court
Fremont, CA 94538

Enclosures
61471706 v1

Appendix 1

PTO's July 30, 2008 letter to FDA



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

JUL 30 2008

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,451,233 was filed on July 25, 2008, under 35 U.S.C. § 156. Please note that this patent expires on October 29, 2008.

The assistance of your Office is requested in confirming that the product identified in the application, XIENCE™ V EECSS (everolimus eluting coronary stent system), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved.¹ Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

¹The filing of the application on July 25, 2008, was timely, given the NDA approval date of July 2, 2008. Applicant, however, misidentified at section 5 on page 3 of the application the last day the application may be submitted as August 31, 2008, pursuant to 37 C.F.R. § 1.740(a)(5). Under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA approval date. The absolute deadline for filing the present PTE Application is thus August 30, 2008, or sixty days from July 2, 2008, starting the count of the sixty-day period on July 2, 2008. The Federal Circuit in *Unimed, Inc. v. Quigg*, 12 USPQ2d 1644, 1646, made clear that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date."

U.S. Patent No. 5,451,233

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Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

A handwritten signature in cursive script, appearing to read "Mary C. Till", is written over a horizontal line.

Mary C. Till

Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner

for Patent Examination Policy

cc: Daniel J. Hulseberg
BAKER BOTTS LLP
30 Rockefeller Plaza
New York, NY 10112-4498

Appendix 2

Company	Product Name	PMA No.	Approval Date
Advanced Cardiovascular Systems	ACS RX Alpha Coronary Dilatation Catheter	P810046 Supp. S067	April 20, 1990
Advanced Cardiovascular Systems	ACS RX Alpha Prime Coronary Dilatation Catheter	P810046 Supp. S071	May 30, 1990
Advanced Cardiovascular Systems	ACS RX Alpha™ .014 Coronary Dilatation Catheter	P810046 Supp. S081	August 23, 1990
Advanced Cardiovascular Systems	ACS® RX Perfusion™ Coronary Dilatation Catheter	P810046 Supp. S079	October 4, 1990
Advanced Cardiovascular Systems	ACS RX® - .014 Coronary Dilatation Catheter	P810046 Supp. S083	October 5, 1990
Advanced Cardiovascular Systems	ACS RX Alpha™ .014 Coronary Dilatation Catheter	P810046 Supp. S093	November 14, 1990
Advanced Cardiovascular Systems	ACS RX Alpha .014 Quarter Size Balloon Catheter	P810046 Supp. S101	April 25, 1991
Advanced Cardiovascular Systems	ACS RX Alpha™ .018 Coronary Dilatation Catheter	P810046 Supp. S096	May 30, 1991
Advanced Cardiovascular Systems	ACS RX Alpha™ .010 Coronary Dilatation Catheter	P810046 Supp. S098	June 27, 1991
Advanced Cardiovascular Systems	ACS RX Alpha Coronary Dilatation Catheter	P810046 Supp. S108	August 6, 1991
Advanced Cardiovascular Systems	ACS RX® Alpha .014 Coronary Dilatation Catheter	P810046 Supp. S105	August 15, 1991
Advanced Cardiovascular Systems	ACS® RX Streak™ Coronary Dilatation Catheter	P810046 Supp. S116	March 24, 1992
Advanced Cardiovascular Systems	ACS RX Perfusion Coronary Dilatation Catheter Add 2.0	P810046 Supp. S121	July 10, 1992
Advanced Cardiovascular Systems	ACS RX Streak™ .014 Coronary Dilatation Catheter	P810046 Supp. S132	October 1, 1992

Advanced Cardiovascular Systems	ACS® Flowtrack™ 40 Coronary Dilatation Catheter	P810046 Supp. S118	October 29, 1992
Advanced Cardiovascular Systems	ACS RX Perfusion™ Coronary Dilatation Catheter	P810046 Supp. S133	November 5, 1992
Advanced Cardiovascular Systems	ACS RX Streak™ Dilatation Catheter	P810046 Supp. S129	February 11, 1993
Advanced Cardiovascular Systems	ACS RX Streak™ .010 Coronary Dilatation Catheter	P810046 Supp. S135	February 11, 1993
Advanced Cardiovascular Systems	ACS RX Perfusion™ Dilatation Catheter	P810046 Supp. S138	May 4, 1993
Advanced Cardiovascular Systems	RX Elipse & Elipse II Coronary Dilatation Catheters	P810046 Supp. S127	September 14, 1993
Advanced Cardiovascular Systems	RX Elipse™ .014 Coronary Dilatation Catheter	P810046 Supp. S140	October 21, 1993
Advanced Cardiovascular Systems	RX Primaflow™ Coronary Dilation Catheter	P810046 Supp. S131	June 14, 1994
Advanced Cardiovascular Systems	RX Flowtrack™ Long Coronary Dilatation Catheter	P810046 Supp. S148	July 11, 1994
Advanced Cardiovascular Systems	RX Elipse™ .014 Coronary Dilatation Catheter	P810046 Supp. S149	August 4, 1994
Advanced Cardiovascular Systems	RX Flowtrack Long™ Coronary Dilatation Catheter	P810046 Supp. S152	November 14, 1994
Advanced Cardiovascular Systems	RX Lifestream™ Coronary Dilatation Catheter	P810046 Supp. S153	March 23, 1995
Advanced Cardiovascular Systems	RX Lifestream™ Coronary Dilatation Catheter	P810046 Supp. S154	June 14, 1995
Advanced Cardiovascular Systems	RX Lifestream PTCA Catheters	P810046 Supp. S160	December 28, 1995
Advanced Cardiovascular Systems	RX Lifestream PTCA Catheters with 30 mm Balloon Length	P810046 Supp. S161	July 29, 1996
Guidant	ACS RX Streak	P810046	November 5, 1996

		Supp. S162	
Guidant	ACS RX Comet™ Coronary Dilation Catheter	P810046 Supp. S166	November 18, 1996
Guidant	ACX RX Comet VP Coronary Dilatation Catheter	P810046 Supp. S169	February 4, 1997
Guidant	ACS RX Comet Coronary Dilation Catheter	P810046 Supp. S171	May 12, 1997
Guidant	ACS RX Lifestream	P810046 Supp. S175	July 3, 1997
Guidant	ACS RX Lifestream	P810046 Supp. S176	July 17, 1997
Guidant	ACS RX Esprit	P810046 Supp. S177	September 19, 1997
Guidant	ACS RX Rocket™ Coronary Dilatation Catheters	P810046 Supp. S179	November 7, 1997
Guidant	ACS RX Rocket Coronary Dilation Catheter	P810046 Supp. S183	May 14, 1998
Guidant	ACS RX Comet VPT™ Coronary Dilatation Catheter/Hydrocoat Hydrophilic	P810046 Supp. S185	June 8, 1998
Guidant	ACS RX Esprit Coronary Dilation Catheter	P810046 Supp. S190	July 30, 1998
Abbott Vascular - Cardiac Therapies	ACS RX Solaris Coronary Dilatation Catheter	P810046 S192	October 16, 1998
Abbott Vascular - Cardiac Therapies	RX Chassis 1 Coronary Dilatation Catheter	P810046 S203	January 11, 2001
Guidant	Voyager RX Coronary Dilatation Catheter	P810046 Supp. S216	June 18, 2004
Abbott Vascular - Cardiac Therapies	RX Chassis 3 Coronary Dilatation Catheter	P810046 Supp. S215	July 16, 2004

Appendix 3

Company	Product Name	PMA No.	Approval Date
Abbott Vascular Inc.	ACS Multi-Link™ Coronary Stent System	P970020	October 2, 1997
Guidant	ACS Multi-Link RX Duet™ Coronary Stent Systems	P970020 Supp. S004	November 5, 1998
Guidant	ACS Multi-Link RX Tristar Coronary Stent System	P970020 Supp. S017	December 22, 1999
Guidant	Multi-Link RX Ultra Coronary Stent System	P970020 Supp. S021	September 8, 2000
Guidant	Multi-Link RX Tetra™ Coronary Stent System	P970020 Supp. S023	October 3, 2000
Guidant	Multi-Link RX Penta Coronary Stent System	P970020 Supp. S027	May 7, 2001
Guidant	ACS Multi-Link RX Pixel Coronary Stent System	P970020 Supp. S030	June 1, 2001
Guidant	Multi-Link RX Zeta Coronary Stent System	P970020 Supp. S042	September 13, 2002
Guidant	Multi-Link RX Vision Coronary Stent System	P020047	July 16, 2003

From: Origin ID: PAOA (650)326-2400
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 379 Lytton Ave

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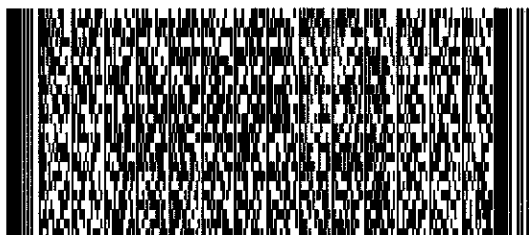
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