

**Appendix 1: 510(k) Summary per 21CFR §807.92****AUG 12 2008****Submitter's  
information**

Stereotaxis, Inc.  
4320 Forest Park Ave, Suite 100  
St. Louis, MO 63108  
Contact: Dennis Pozzo, Regulatory Affairs Specialist  
Phone: 314-678-6136  
February 27, 2008

**Device/  
classification  
name**

- Device Name:
  - PowerAssert™ Radiofrequency Guidewire (PARG)
- Classification/Common name:
  - Catheter Wire Guide
- The marketed device(s) to which substantial equivalence is claimed:
  - Baylis Medical's RF Tuner Wire – 510(k), K051670
  - Cronus Guidewire – 510(k), K042854
  - Assert Guidewire – 510(k), K043457

**Device  
description**

The PARG is a sterile, single use, magnetically steerable endovascular guidewire intended to create a channel through occlusive material in vessels using mechanical or radiofrequency energy. Once a channel is created this will allow the introduction of adjunct devices/therapies to more completely alleviate the occlusion.

**Intended use**

The PowerAssert™ Radiofrequency Guidewire (PARG) is intended for use with a Stereotaxis Niobe Magnetic Navigation System for the recanalization of occluded peripheral vessels.

*Continued on next page*

## Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

### Technological characteristics

The table below lists device characteristics.

Device Characteristic	Proposed PARG K080637	Predicate Baylis RF Tunneler Wire K051670	Predicate Stereotaxis Cronus® & Assert™ Guidewires K042854 & K043457
Intended Use	The PowerAssert™ Radiofrequency Guidewire is intended for use in recanalization of occluded peripheral vessels.	The RF Tunneler Wire is intended to create a channel in totally occluded peripheral vessels 3mm or greater.	The guidewires are intended to introduce and position over-the-wire catheters and other over-the-wire therapeutic devices within the coronary and peripheral vasculature during PTCA or other intravascular interventional procedures.
RF Capable	Yes	Yes	No
Magnetic Navigation Capable	Yes	No	Yes
Wire Diameter	0.018"	0.035"	0.014"
Wire Length(s)	185 and 300 cm	250 cm	180, 210, 235 & 300 cm
Max. RF Power	25 watts	25 watts	NA
RF Dwell Time	3 seconds	99 seconds	NA
Sterilization Method	EtO	EtO	EtO
Single Use	Yes	Yes	Yes
Distal Tip Lubricious Coating	Hydrophilic	Hydrophilic	Hydrophilic
Energy Source	Baylis' RF Generator	Baylis' RF Generator	NA

### Performance data

Based upon the objective evidence presented in this 510(k) it has been demonstrated that the PARG is substantially equivalent to the predicate devices it has been compared to in this submission.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 12 2008

Stereotaxis, Inc.  
c/o Mr. Dennis Pozzo  
4320 Forest Park Avenue, Suite 100  
St. Louis, MO 63108

Re: K080637  
Trade/Device Name: PowerAssert Radiofrequency Guidewire  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter guide wire  
Regulatory Class: Class II (two)  
Product Code: DQX  
Dated: July 29, 2008  
Received: July 30, 2008

Dear Mr. Pozzo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

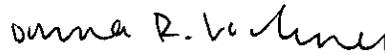
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Appendix 2: Indications for Use Statement

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**Statement**

The indications for Use Statement:

510(k) Number: K080637

Device Name: PowerAssert™ Radiofrequency Guidewire

The PowerAssert™ Radiofrequency Guidewire (PARG) is intended for use with a Stereotaxis Niobe Magnetic Navigation System for the recanalization of occluded peripheral vessels.

Prescription Use  X  AND/OR Over-The-Counter Use    
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON  
ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Diana P. Vachner  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K080637