Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)? No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.? Yes. The Spectra Guidewire Introducer Needle is substantially equivalent design, materials, and method of use. The basic fundamental scientific technology of the device has not changed.

Could the new characteristics affect safety or effectiveness? No.

Do the new characteristics raise new types of safety and effectiveness questions? No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics? Yes.

Sterilization requirements of ISO 11135:2007, *Sterilization of Health Care Products - Requirements for Validation and Routine Control -- Ethylene Oxide Sterilization.*

Biocompatibility requirements according to of ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.*

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

Are performance data available to assess effects of new characteristics? Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards and protocols.

Do performance data demonstrate equivalence? Yes. Performance data gathered demonstrated that the Spectra Guidewire Introducer Needle is substantially equivalent to the noted predicate devices.

CONCLUSION

The ***Spectra Guidewire Introducer Needle*** will meet all established acceptance criteria for performance testing. This testing demonstrated that the ***Spectra Guidewire Introducer Needle*** is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the following predicate devices ***Teleflex Medical Introducer Needle (K851140), and Cook Percutaneous Entry Needle (Pre-amendment device, Reference Medical Device Listing No. 187040).***

Regulation Number:	21 CFR 870.4500
Proprietary Name:	***Cook Percutaneous Entry Needle (Pre-amendment device, Reference Medical Device Listing No. 187040)***
Regulation Name:	Instruments, Surgical, Cardiovascular
Common/Usual Name:	Guidewire Introducer Needle
Classification Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	DWS
Regulation Number:	21 CFR 870.4500

DEVICE DESCRIPTION:

The Spectra Guidewire Introducer Needle consists of a stainless steel needle and a colored translucent standard female Luer lock hub locking connector for rapid (flashback) visualization. The Spectra Guidewire Introducer Needle is available in a single-wall style with or without a Seldinger shield. The stainless steel needles are available with and without an echogenic feature. The needles are available in a range of wall thicknesses, gauges and lengths to match the end-user need.

Spectra Guidewire Introducer Needles will be marketed as sterile, non-pyrogenic, and single use devices. Additionally, the device will be marketed as a guidewire introducer needle for use as an accessory in procedure kits. In the case of being used in procedural kits, the product will be shipped bulk non-sterile to the kitting manufacturer. The Spectra Guidewire Introducer Needle will be incorporated into the procedure kit, packaged and sterilized.

INTENDED USE:

The Spectra Guidewire Introducer Needle is intended to be used by medical professionals as introducers/cannula for percutaneous introduction and placement of guidewires in vascular procedures.

INDICATIONS FOR USE:

The Spectra Guidewire Introducer Needle is indicated for percutaneous introduction and placement of guidewires in vascular procedures.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

New device is compared to Marketed Device? Yes. It is compared to legally marketed predicates.

Does the new device have the same indication statements? Yes.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92)
for *Spectra GUIDEWIRE INTRODUCER NEEDLE*

SUBMITTER:
Spectra Medical Devices, Inc.
260-H Fordham Road
Wilmington, **Massachusetts, 01887**

ESTABLISHMENT REGISTRATION NUMBER:
1224960

CONTACT:
Agustin Turriza
QA/RA Manager
Telephone: (978) 657-0889
Fax: (978) 657-4339
Email: **aturriza@SpectraMedical.com**

DATE PREPARED:
August 21, 2008

NAME OF MEDICAL DEVICE:

Proprietary Name:	***Spectra Guidewire Introducer Needle***
Regulation Name:	Introducer, Catheter
Common/Usual Name:	Guidewire Introducer Needle

DEVICE CLASSIFICATION:

Classification Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	DYB
Regulation Number:	21 CFR 870.1340

PREDICATE DEVICES:

Proprietary Name:	***Teleflex Medical Introducer Needle (K851140)***
Regulation Name:	Instruments, Surgical, Cardiovascular
Common/Usual Name:	Guidewire Introducer Needle
Classification Panel:	Cardiovascular
Regulatory Class:	Class II
Product Code:	DWS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 8 2008

Mr. Agustin Turriza
Quality Assurance/Regulatory Affairs Manager
Spectra Medical Devices, Incorporated
260-H Fordham Road
Wilmington, Massachusetts 01887

Re: K082580
Trade/Device Name: Spectra Guidewire Introducer Needle
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II
Product Code: DYB
Dated: August 27, 2008
Received: September 9, 2008

Dear Mr. Turriza:

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) 276-0115. 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 Biometric's (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,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K982580

Indications For Use

510(k) Number (if known): _____

Device Name: ***SPECTRA GUIDEWIRE INTRODUCER NEEDLE***

Indications For Use:

The Spectra Guidewire Introducer Needle is indicated for percutaneous introduction and placement of guidewires in vascular procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K982580