K090272

MAR 1 8 2009

CardinalHealth

1430 Waukegan Road
McGaw Park, Illinois 60085-6787
847.578.6442
FAX: 847.785.2506

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
As required by section 807.92(c)
Spetzler Snap-On/Slide-On Scalp Retractor Clamps

Sponsor:	Cardinal Health 1430 Waukegan Road MPKB McGaw Park, IL 60085
Regulatory Affairs Contact:	Gina Rajterowski
Telephone:	(847) 578-6442
Fax:	(847) 785-2506
Date Summary Prepared:	January 2009
Device Name	Spetzler Snap-On/Slide-On Scalp Retractor Clamps
Common Name	Clamp accessory used for self-retaining retraction
Classification Name	Self-retaining retractor for neurosurgery (21 CFR, 882.4800, Product Code GZT)
Predicate Device(s)	Rhoton-Merz Self-Retaining Brain Retractor System, K895395 Leyla Self-Retaining Brain Retractor System, Preamendment device

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Description:	The Spetzler Snap-On/Slide-On Scalp Retractor Clamps are surgical accessories that affix to the appropriately sized surgical bars surrounding the patient's head during neurosurgical procedures. The clamps interact with elastic scalp retraction hooks to assist with the self-retaining retraction of the scalp during neurosurgical procedures. The clamps are offered in two versions (Snap-On and Slide-On) and each version is offered in two sizes (0.5" and 20mm) to accommodate most commonly used surgical accessory bars.
Intended Use:	The Spetzler Snap-On/Slide-On Scalp Retractor Clamps are accessories that are intended to be used to assist in the retraction of the scalp during all supratentorial and infratentorial skull operations.
Summary of Technological Characteristics:	The proposed device and the predicate devices are composed of the same or similar principals of operation, design, materials and manufacturing characteristics.
Summary of Testing:	The Spetzler Snap-On/Slide-On Scalp Retractor Clamps were evaluated in non-clinical tests under various conditions to assess the design performance and conformance to design specifications.
Non-Clinical Testing	Performance testing demonstrated that the proposed device is substantially equivalent to the currently marketed predicate devices with regard to functional characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2009

Cardinal Health
c/o Gina Rajterowski
Regulatory Affairs Manager
1430 Waukegan Road
McGaw Park, IL 60085-6787

Re: K090272
Trade/Device Name: Spetzler Snap-On/Slide-On Scalp Retractor Clamps
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-retaining retractor for neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: March 4, 2009
Received: March 9, 2009

Dear Ms. Rajterowski :

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.

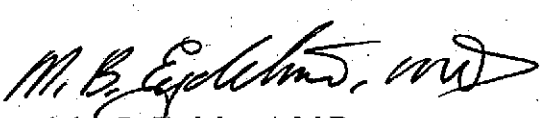
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardinalHealth

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Indication for Use

510(k) Number (if known):

Device Name: Spetzler Snap-On/Slide-On Scalp Retractor Clamps

Indications For Use: **The Spetzler Snap-On/Slide-On Scalp Retractor Clamps are accessories that are intended to be used to assist in the retraction of the scalp during supratentorial and infratentorial skull operations.**

Prescription Use _X_ or Over-The Counter Use _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

510(k) Number K090272