K994191

FEB 8 2000

NMT Medical Inc. Premarket 510(k) Notification

510(k) Summary of Safety and Effectiveness

in Accordance with SMDA of 1990
21 CFR 807.92

Spetzler™ Round Handle Aneurysm Clip Appliers

Sponsor

NMT Medical, Inc.
27 Wormwood Street
Boston, MA 02210-1625

Contact

Sherrie Coval Goldsmith, VP Regulatory Affairs
Phone: 617-737-0930
Fax: 617-737-0932
email: scg@nmtmedical.com

Submitted Device

Trade Name:	Spetzler™ Round Handle Appliers
Common Names:	Clip Appliers Applying Forceps Aneurysm Clip Appliers
Classification Name:	Applier, Aneurysm Clip
Product Code:	84 HCI
Product Classification:	II
Regulatory Classification:	21 CFR 882.4175

General Information

Device Description: There are two types of Spetzler™ Round Handle Appliers; Stainless Steel with Titanium Jaws and Pads and completely Titanium. Each type applier has two styles; straight and bayonet.

Intended Use: Indications for and intended use of the aneurysm clip applier is to hold and sufficiently open the aneurysm clip for application during aneurysm repair surgery. The device is used to deliver the aneurysm clip to the site of the aneurysm.

The Spetzler™ Round Handle Applier is designed for use only with the Spetzler™ Titanium Aneurysm Clips.

Summary of Technological Characteristics

The new Spetzler™ round Handle Appliers do not impart any new technological feature in design or manufacturing. It is the same as to function and intended use when compared to the predicates. The Spetzler™ Clip Appliers is different in that its spring loaded squeeze mechanism is more compact than the "box" style. Therefore latch engagement and disengagement requires less travel.

Performance Data

No applicable performance standards have been promulgated under Section 514 of the FD&C Act for these devices.

The respective Spetzler™ Round Handle Appliers presented in this submission do conform to the following standards:

ASTM B348-97	Standard Specification for Titanium and Titanium Alloy Bars and Billets
ASTM F700-93	Standard Practice for Care and Handling of Intracranial Aneurysm Clips and Instruments
ISO 5832 Part 3, 1978	Implants for Surgery - Metallic materials Part 3: wrought titanium 6-aluminum 4-vanadium alloy

ISO 7153-1:1991	Surgical Instruments - Metallic materials Part 1: Stainless Steel

Substantial Equivalence

NMT Medical, Inc. believes that the Spetzler™ Round Handle Appliers are substantially equivalent in design, material composition, function and intended use as the following clip appliers currently in commercial distribution and cleared by the FDA:

Elekta Clip Appliers	(Elekta)	(K955064)
Aesculap Axial Clip Appliers	(Aesculap)	(K984109)
Yasargil, Caspar, Vario Clip Appliers	(Aesculap)	(K940970)
Sundt Slim-Line Aneurysm Clip Applier	(J & J Prof, Inc.)	(K982379)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 2000

NMT Medical, Inc.
c/o Mr. Ronald D. Arkin
Arkin & Associates
1733 Canton Lane
Marietta, Georgia 30062

Re: K994191
Trade Name: Spetzler™ Round-Handled Applier
Spetzler™ Round Handled Aneurysm Clip Applier
Regulatory Class: II
Product Code: HCI
Dated: December 10, 1999
Received: December 13, 1999

Dear Mr. Arkin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use

Revised February 2, 2000

510(k) Number (if known): **K994191**

Device Name: Spetzler™ Round-Handled Applier
Spetzler™ Round-Handled Aneurysm Clip Applier

Indications for Use:

Indications for and intended use of the aneurysm clip applier is to hold and sufficiently open the aneurysm clip for application during intracranial aneurysm repair surgery. The device is used to deliver the aneurysm clip to the site of the intracranial aneurysm.

The Spetzler™ Round-Handled Applier is designed for use only with the Spetzler™ Titanium Aneurysm Clips.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

NPO for JZD

(Division Sign-Off)
Division of General Restorative Devices

(Optional Format 3-10-98)

510(k) Number K994191

Prescription Use YES
(Per 21 CFR 801.109)