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JUN 2 0 2003

CardinalHealth

1500 Waukegan Road, Building MPWM
McGaw Park, IL 60085
tel 847.578.3312
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SUMMARY OF SAFETY AND EFFECTIVENESS

Temporary Titanium Aneurysm Clip
(As Required by 21 CFR §807.92)

Manufacturer:	Cardinal Health Medical Products and Services V. Mueller
Regulatory Affairs Contact	Lance Marconi 1500 Waukegan Road McGaw Park, Illinois 60085
Telephone:	(847) 578-3312
Date Summary Prepared:	May 7, 2003
Product Trade Name:	Temporary Titanium Aneurysm Clip
Common Name:	Aneurysm Clip
Classification:	Clip, Aneurysm
Predicate Device: **(K991959)**	PSI Titanium Aneurysm Clip
Description:	The temporary titanium aneurysm clip is bent wire that provides a spring operated, self-closing aneurysm clip of various lengths/sizes.
Intended Use:	Placement in the intracranial space for the temporary occlusion of cerebral aneurysms and vessels to facilitate permanent occlusion. Placement of the clip requires the use of especially designed appliers.

Substantial Equivalence:

The Temporary Titanium Aneurysm Clip is substantially equivalent to the Titanium Aneurysm Clip by Cardinal Health in that the:

- Intended use is the same
- Material
- Clip Styles

Summary of Testing:

Titanium material certification to ASTM F136-98, repeat sterilization performance study was conducted to ensure no adverse effect on closing force for the Temporary Titanium Aneurysm Clips and all acceptance criteria were met.

Summary of Testing:

Sterilization Performance studies were conducted for the Temporary Titanium Aneurysm Clip and all acceptance criteria were met.

Conclusion:

The Temporary Titanium Aneurysm Clip is safe and effective for it's intended use and meets all regulatory requirements to be found substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2006

Cardinal Health
% Mr. Lance Marconi
Manager, Regulatory Affairs
1500 Waukegan Road, Building MPWM
McGaw Park, Illinois 60085

Re: K031468
Trade/Device Name: Temporary Titanium Aneurysm Clip
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm clip
Regulatory Class: II
Product Code: HCH, HCI
Dated: May 7, 2003
Received: May 9, 2003

Dear Mr. Marconi:

This letter corrects our substantially equivalent letter of January 20, 2003.

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 (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 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 continue 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardinalHealth

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K031468

INDICATIONS FOR USE

510(k) Number (if known): Unknown

Device Name: Temporary Titanium Aneurysm Clip

Indication For Use: Temporary placement in the brain to facilitate occlusion of cerebral aneurysms. Clips are only to be applied with V. Mueller titanium coated clip appliers.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031468

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or **Over-The Counter Use** _____