



AUG 12 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GEISTER MEDIZINTECHNIK GmbH
c/o Mr. Dagmar Maser
Business Support International
Amstel 320-I
Netherlands 1017 AP

Re: K030788
Trade Name: GEISTER Vessel Dilators
Regulation Number: 21 CFR 870.4475
Regulation Name: Surgical vessel dilator
Regulatory Class: Class II (two)
Product Code: DWP
Dated: June 20, 2003
Received: June 23, 2003

Dear Mr. Maser:

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

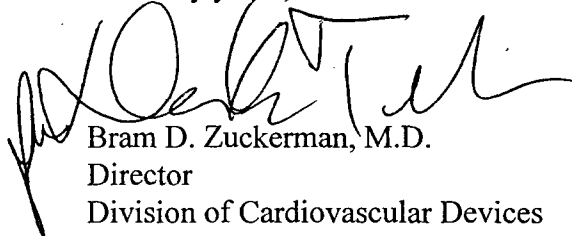
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Office of Compliance at (301) 594-4646. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure


510(k) Number K 030788
 Device Name **GEISTER Vessel Dilators**
 Classification/CFR **74 DWP / 870.4475**

INDICATIONS FOR USE

GEISTER vessel dilators are devices used to enlarge or calibrate vessels during coronary artery bypass or angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels, and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.

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

Concurrence of CDREH, Office of Device Evaluation (ODE)



 (Division Sign-Off)
 Division of Cardiovascular Devices
 510(k) Number K 030788

Prescription Use _____
 (Per CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)