K053463

MAR 7 2006

510(K) SUMMARY
AiM Accuracy In Marking®

Date:	December 4, 2005
Owner/Operator:	Georgene Austria 5755 Valerie Avenue Woodland Hills, CA 91367
Contact Person:	George Austria Owner
Contract Manufacturer:	Griff Industries 19761 Bahama Street Northridge, CA 91324 FDA Registration # 2031528
Device Trade Name:	AiM Accuracy In Marking® System
Common Name:	Accessory to an Ultrasound Transducer
Classification Name:	Class II, 90ITX and Accessories
Regulatory Reference:	892.1570
Predicate Device:	Sandel Medical Industries, LLC Skin Marker Class 1 exempt device under 878.4660 FZZ
Intended Use and indication for use:	The marking device is enables the sonographer to mark the "targeted" vessel during vascular mapping. The shadow guide is an adhesive "film" adhered directly underneath the footing of the transducer used as guide on identifying the vessel. The marking device and the "shadow guide" are attached to a transducer using a non-latex adhesive. The device shall be sold non-sterile for single use only. This device is compatible with FDA approved linear and curved linear ultrasonic transducers in the frequency of 4MHz to 12MHz.

Principle of Operation: Transducer Shadow Guide

Transducer
Ultrasound transducers emit mechanical sound waves which are transmitted into human tissue through a coupling medium. As the sound wave propagates through the tissue, a portion of the sound wave is reflected and a portion of the sound wave is transmitted

dependent upon the acoustic properties of the tissue it encounters. Tissues with significant disparities in acoustic properties create a tissue interface that promotes a strong reflection of the sound wave due to an acoustic impedance mismatch. The reflected sound wave termed echo is detected by the transducer and the echo signal is processed electronically by the ultrasound system.

Shadow Guide

When the Shadow Guide is applied to the footprint of a transducer, the Shadow Guide creates an acoustic impedance mismatch as the sound wave propagates from the footprint of the transducer to the Shadow Guide. The sound wave is completely reflected specifically in the clear areas of the Shadow Guide producing 2 delineated reference lines in the ultrasound image.

Summary of Similarities and Differences:

Similarities:

The following are similarities between Sandel Medical Industries Skin Marker and AiM Marking device

- Both devices are skin markers
- Both devices are single use only
- Both devices use the same ink (gentian violet)
- Both devices are Class 1 exempt devices

Differences

The following are differences between Sandel Medical Skin marker and AiM Marking Device

- The shape of the devices are different
- The internal components are different
- The AiM Marking device includes a shadow guide for identifying target vessels.
- The AiM Marking device shall be sold non-sterile while skin markers are available sterile and non sterile

Conclusion:

The proposed marking device is comparable to the predicate device (Skin Marker). Although there is no identified predicate device for the shadow guide, the simplicity of the design as well as test data demonstrates that safety and effectiveness of the function of the transducer is not affected by the shadow guide. The shadow guide's function is beneficial on identifying the target vessel during vascular mapping.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 2006

Ms. Georgene Austria
Official Correspondent
5755 Valerie Avenue
WOODLAND HILLS CA 91367

Re: K053463
Trade/Device Name: Accuracy In Marking®
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX and FZZ
Dated: December 4, 2005
Received: December 20, 2005

Dear Ms. Austria:

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 (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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Applicant: Georgene Austria
510(k) Number: k053463

Device Name: Accuracy In Marking®

Indication For Use
Accuracy In Marking® is a marking device used in conjunction with a transducer during vascular mapping. The device allows the user to mark a vascular area immediately when it is identified during mapping process. The guide path underneath the transducer allows the user to identify the target vessel prior to marking.

The product is supplied non-sterile and is intended for single use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use ____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number k053463