AUG - 8 2003

5 510(k) Summary

This summary of the 510(k) premarket notification for the Vista Scientific Barium Sulfate is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Manufacturer

Vista Scientific, LLC
7960 Niwot Road, Unit B-7
Niwot, CO 80503
Telephone: (303) 652-1501
Registration #: FDA forms 2891 and 2892 submitted.
FDA letter acknowledging receipt of forms received 6 May 2003.

Contact Person

Jonathan Modine
General Manager

Date Prepared

August 1, 2003

Device Classification Name

Accessory, Barium Sulfate, Methyl Methacrylate For Cranioplasty, Product Code MYU (Class II)

Trade Name

Vista Scientific AxioView Barium Sulfate™

Generic/Common Name

Barium Sulfate USP

Predicate Device

Biotrace® Bone Cement Radio-Opacifier (Bryan Corporation) (K002063)

Action taken to comply with Section 514 of the Act

No applicable mandatory performance standards or special controls exist for this device.

Intended Use

Vista Scientific Barium Sulfate™ is intended for use as an additive to Codman Cranioplastic™ (Type 1-Slow set) to provide radiopacity for imaging purposes.

Product Description

Vista Scientific Barium Sulfate is a dry powder supplied sterile and non-pyrogenic for use as a radiopacifying additive to Codman Cranioplastic™ (Type 1-Slow set) bone cement. The Barium Sulfate is supplied in a quantity of 6 grams, packaged in a closed 120 mL polymer container, and sealed within a double sterile peel pouch package configuration.

Substantial Equivalence

Vista Scientific Barium Sulfate is intended for use as an additive to Codman Cranioplastic™ (Type 1-Slow set) to provide radiopacity for imaging purposes.

It is substantially equivalent to other devices currently on the market for use as a radiopacifying additive for imaging purposes when used as an additive to Codman Cranioplastic™ (Type 1-Slow set).

Vista Scientific Barium Sulfate is equivalent to Biotrace® Bone Cement Radio-Opacifier (Bryan Corporation, K002063). Vista Scientific Barium Sulfate is substantially equivalent to the predicate device with regards to device design, intended use, patient population and anatomical site. Any differences in technological characteristics between the Vista Scientific Barium Sulfate and the predicate device do not raise any new issues of safety or effectiveness.

Testing in Support of Substantial Equivalence

Performance, biocompatibility and microbiological testing have been conducted, and the results of the testing verify that the Vista Scientific Barium Sulfate performs as designed and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Mr. Jonathan Modine
General Manager
Vista Scientific, LLC
7960 Niwot Road
Unit B-7
Niwot, CO 80503

Re: K024359
Trade Name: Vista Scientific Barium Sulfate ™
Regulation Number: 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: Class II
Product Code: MYU
Dated: June 3, 2003
Received: June 25, 2003

Dear Mr. Modine:

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 Office of Compliance at (301) 594-4639. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Statement of Indications for Use

INDICATIONS FOR USE

510(k) Number (if known): K024359

Device Name: Vista Scientific Barium Sulfate™

Indications for Use:

Vista Scientific Barium Sulfate™ is intended for use as an additive to Codman Cranioplastic™ (Type 1-Slow set) to provide radiopacity for imaging purposes.

(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) (Optional Format 1-2-96)

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

510(k) Number K024359