K042414

DEC 2 9 2004

Visioplast Acrylic Resin
Traditional 510(k)

Company confidential

Summary of Safety and Effectiveness

Company:

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General Manager

Official Correspondent

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1. Proposed Propietary Trade Name: Visioplast Acrylic Resin

2. Classification Name: Methyl methacrylate for cranioplasty.

3. Equivalent Device:
The subject device is substantially equivalent to Codman Cranioplastic ™, Acrylic Cranioplasty Material (#K873689)

4. Product Description:
Visioplast Acrylic Resin is a self-curing resin which is intended for the repair of cranial defects. Like the predicate model, the proposed acrylic resin is provided sterile and contains a liquid and powder component. Visioplast Acrylic Resin is designed for manual mixing technique. When the two components are mixed together, a viscous paste is obtained which hardens within 20 minutes with a cold-curing polimerisation.
The chemical constituents are substantially equivalent to those in the predicate apart from the presence of barium sulphate in the powder which provides radiopacity for imaging purposes.

5. Indications
Visioplast Acrylic Resin is a resinous material for repairing cranial defects.

Summary of Safety and Effectiveness

6. Substantial Equivalence

Based on the product performance information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 9 2004

Christine Brauer, Ph.D.
Regulatory Affairs Consultant
One Democracy Plaza
6701 Democracy Boulevard, Suite 700
Bethesda, Maryland 20817

Re: K042414
Trade Name: Visioplast Acrylic Resin
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: II
Product Code: GXP
Dated: December 20, 2004
Received: December 21, 2004

Dear Dr. Brauer:

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 (240) 276-0120. 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,

for Mark N. Melkerson

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

Indications for Use

510(k) Number: K042414

Device Names: Visioplast Acrylic Resin

INDICATIONS FOR USE
Visioplast Acrylic Resin is a resinous material for repairing cranial defects.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042414

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over the Counter Use _____