510(k) Summary

JAN 2 2 2003

510(k) Number: K023575

Date Prepared: October 2, 2002

Applicant Information:

Applicant: Immedica, Inc.
100 Passaic Ave.
Chatham, NJ 07928

Contact: Roy B. Bogert
VP, Engineering & Regulatory Affairs

Phone: (973) 635-9040
Fax: (973) 635-9878

Device Information:

Trade Name: Concert™ Cranioplast

Common Name: Methyl methacrylate for cranioplasty

Equivalent Devices:
The subject device is substantially equivalent to Codman Cranioplastic™, Acrylic Cranioplasty Material (K873689)

Intended Use:
Concert™ Cranioplast is a resinous material for repair of cranial defects.

Comparison to Predicate Devices:
This device has the same intended use and functional characteristics as the predicate device.

Non-clinical Test Results:
Performance testing demonstrated that Concert™ Cranioplast is substantially equivalent to Cranioplastic with regard to functional characteristics.

Summary:
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

JAN 22 2003

Mr. Roy Bogert
VP, Engineering and Regulatory Affairs
Immedica, Inc.
100 Passaic Avenue
Chatham, NJ 07928-2848

Re: K023575
Trade Name: Immedica Concert™ Cranioplast
Regulation Number: 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: October 23, 2002
Received: October 24, 2002

Dear Mr. Bogert:

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,

for Miriam C Provost

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

510(k) Number (if known): K023575

Device Name: Concert™ Cranioplast

Indications For Use:

Concert™ Cranioplast is a resinous material for repair of cranial defects.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K023575

Prescription Use ____ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)