JUN 17 2004

Confidential

K040860
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Integra Bone Fixation System

510(k) Summary

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536

Contact person and telephone number:

Donna R. Wallace
Director Regulatory Affairs
(609) 275-0500

Date prepared: April 1, 2004

Name of device:

Proprietary Name:	Integra Bone Fixation System
Common Name:	Bone Fixation Plates and Screws
Classification Name:	Bone Fixation Plates
	Bone Fixation Screws
	Burr Hole Covers

Substantial Equivalence:

The Integra Bone Fixation System is substantially equivalent to the commercially distributed predicate devices, the TiMesh® System, the Centre-Drive Drill-Free™ Screws, and the LEIBINGER® Bone Plates and Bone Screws.

Intended Use:

The Integra Bone Fixation System is intended for use in internal fixation of small bones affected by trauma or for reconstruction or arthrodesis. Burr hole cover plates are intended specifically to cover burr holes and to secure cranial flaps.

Device Description:

The Integra Bone Fixation System includes titanium self-tapping and/or self-drilling screws and plates along with instruments for the internal fixation of bone fragments. The fixation screws are supplied in a variety of diameters and lengths designed to fit Integra's various designs of fixation plates and burr hole covers. The Integra Bone Fixation System includes reusable instruments such as screwdrivers, handles and blades, plate holders, drill bits and instrument trays. The single use fixation plates and screws, and the reusable instruments are provided non-sterile and must be sterilized prior to use. The basic design, intended use, materials, and principles of operation of the Integra Bone Fixation System are equivalent to the predicate devices.

Conclusion:

The Integra Bone Fixation System is substantially equivalent to other commercially marketed devices and does not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Donna R. Wallace, RAC
Director, Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K040860
Trade/Device Name: Integra Bone Fixation System
Regulation Numbers: 21 CFR 888.3030, 21 CFR 888.3040, 21 CFR 882.5330
Regulation Names: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener, Preformed nonalterable cranioplasty plate
Regulatory Class: II
Product Codes: HRS, HWC, GXN
Dated: April 1, 2004
Received: April 2, 2004

Dear Ms. Wallace:

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) 594-4659. 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 (if known): K041860

Device Name: Integra Bone Fixation System

Indications For Use:

The Integra Bone Fixation System is intended for use in internal fixation of small bones affected by trauma, for reconstruction, or arthrodesis. Burr hole cover plates are intended specifically to cover burr holes and to secure cranial flaps.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

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

510(k) Number K040860