510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The Trabecular Metal Glenoid
Bigliani/Flatow® (B/F) The Complete Shoulder Solution

Submitter Name And Address:	Implex Corp. 80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Robert Poggie, Ph.D.
Phone Number:	(201) 818-1800
Fax Number:	(973) 829-0825
Date Prepared:	August 12, 2003
Device Trade Name:	The Trabecular Metal Glenoid, the B/F Complete Shoulder Solution
Device Common Name:	Glenoid Component
Classification Number and Name:	21 CFR 888.3660 & 888.3650; Prosthesis, shoulder, semi & non-constrained, metal/polymer cemented.

Substantial Equivalence:

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

The device is a monoblock glenoid component comprised of a Trabecular Metal base with an articular surface comprised of direct compression molded polyethylene. This device was cleared in K022377. The TM Glenoid is designed to interface & articulate with Zimmer B/F humeral components and is available in one thickness option of 5 mm, and the same outer profile options as the B/F all-polyethylene glenoid.

510(k) Summary (Continued)

Indications for use: Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; un-united humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights greater than 27 mm may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional non-constrained arthroplasty is not acceptable. The Trabecular Metal Glenoid must be fully or partially cemented in place in the USA.

Device Technological Characteristics & Comparison to Predicate Device: The subject device is identical to the predicate Trabecular Metal Glenoid, and possesses the same articulation geometry, minimum polyethylene thickness and outer profile options as the predicate B/F all-poly glenoid components. The Trabecular Metal, direct compression molded polyethylene and monoblock design is similar to numerous cleared Implex devices. This 510(k) clearance provides for the addition of a partial cementing technique (to the base) to the already cleared, fully cemented technique.

Performance Data: Component stability testing was performed per ASTM F 2080-00 for the subject and predicate devices and cementing techniques. The displacement data indicated equivalence for the partial cementing techniques for the TM Glenoid and the predicate all-poly glenoid for cyclic loading through 3600 cycles.

Conclusion: The Trabecular Metal Glenoid is substantially equivalent to the identified predicate devices identified in this premarket notification based on the similarity in technological characteristics, indications for use, testing per ASTM F 2080-00, and subsequent analysis of the data and tested components and foam materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2003

Robert A. Poggie, Ph.D.
Director, Applied Research
Implex Corp.
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K031449
Trade/Device Name: Trabecular Metal Glenoid for the Bigliani/Flatow, The Complete Shoulder Solution
Regulation Number: 21 CFR 888.3660 and 888.3650
Regulation Names: Shoulder joint metal/polymer semi-constrained cemented prosthesis, and Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Codes: KWS and KWT
Dated: August 12, 2003
Received: August 26, 2003

Dear Dr. Poggie:

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.

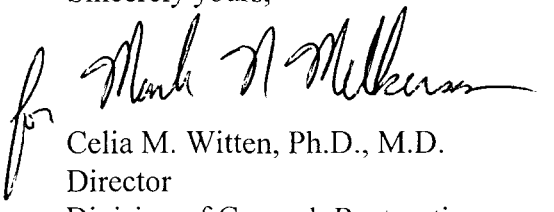
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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): **K031449** Page 1 of 1

Device Name: The Trabecular Metal Glenoid – The B/F Complete Shoulder Solution

Indications For Use:

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for Mark N. Milhous

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

510(k) Number K031449

(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)