k031462
page 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Trabecular Metal Tibial and Patellar Components for the *NexGen* Knee System

Submitter Name:	Implex Corp.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person(s):	Marci Halevi
Phone Number:	(201) 818-1800
Fax Number:	(973) 829-0825
Date Prepared:	May 6, 2003
Device Trade Name:	Trabecular Metal Tibial and Patellar Components for the *NexGen* Knee System
Device Common Name:	Tibial and Patellar Components
Classification Name:	Knee Joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis

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.

510(K) Summary of Safety and Effectiveness - Continued... K03/462

Device Description:

Trabecular Metal Tibial and Patellar Components for the NexGen Knee System are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates cemented or cementless total knee arthroplasty.

These devices are of monoblock construct and are manufactured from Trabecular Metal (Hedrocel Porous Tantalum) and direct compression molded ultrahigh molecular weight polyethylene.

The Trabecular Metal Tibial and Patellar Components for the *NexGen* Knee System articulate with the appropriate Zimmer CR and LPS Femoral Components.

Intended Use:

Trabecular Metal Tibial and Patellar Components for the *NexGen* Knee System are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates cemented or cementless total knee arthroplasty.

Device Technological Characteristics and Comparison to Predicate Device:

The predicate and subject devices are identical; performance characteristics therefore remain as documented in the predicate submissions.

Performance Data:

The NexGen TMT Tibia, LPS Tibia and Primary Porous Patella were all tested per applicable standards and the results demonstrated that the device will perform as intended.

Conclusion:

The Trabecular Metal Tibial and Patellar Components for the *NexGen* Knee System incorporates the identical materials, size options, technological design and geometry features as the legally marketed predicate devices described herein. The single difference is in the Indications for Use and associated changes to the Package Insert and Surgical Protocol, which will now incorporate the option for uncemented use. Review of 21.CFR 888.3565, Special Guidance Document for porous coated uncemented prosthesis, and the pre-clinical testing of the predicate (and subject) devices indicate no additional risk or change in safety or efficacy for the indicated and intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2003

Ms. Marci Halevi
Manager of Regulatory Affairs
Implex Corporation
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K031462
Trade/Device Name: Trabecular Metal Tibial and Patellar Components for the *NexGen* Knee System
Regulation Numbers: 21 CFR 888.3565
Regulation Names: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: MBH
Dated: May 6, 2003
Received: May 8, 2003

Dear Ms. Halevi:

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,

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

510(k) Number (if known): K031462

Device Name: Trabecular Metal Tibial and Patellar Components for the NexGen Knee System

Indications For Use:

Trabecular Metal Tibial and Patellar Components for the *NexGen* Knee System are intended for use where severe degeneration, trauma, or other pathology of the knee joint indicates cemented or cementless total knee arthroplasty.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR... Over-The-Counter Use _____

(Optional Format 1-2-96)

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

510(k) Number K031462