MAY - 4 2000

K994126

510(k) Summary of Safety and Effectiveness

October 15, 1999

Trade name: MODULAR-PLUS Revision Stem

Common name: Hip Stem Prosthesis

Classification name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR 888.3360 (87 LWJ

Equivalence: LINK MP Reconstruction Hip Stem (K-955296, SE date 02/14/96)

Characteristics: The MODULAR-PLUS Revision Stem is a cement-less, two-part modular system that consists of a distal anchorage module and a proximal revision module. These two modules are connected with a multi-staged conical coupling and fitted with a safety screw. Taken together, the two modules again form a long, quadrilateral, conical stem prosthesis, which can be anchored in the distal half of the femur. The range consists of 12 distal and 6 proximal modules of various sizes. The distal module has a symmetrical curve matching the forward curve of the femur, suitable for the right and left femur. The proximal module offers a choice of standard and long modules in order to achieve the appropriate geometry of the stem and acetabulum. It is placed on top of the firmly embedded distal module and is fully adjustable to the appropriate degree of anteversion. Both modules (proximal and distal) and the safety screw are made of titanium (TiAl6Nb7) in conformance with ASTM-F 1295-92 and ISO 5832-11.

Indications: The MODULAR-PLUS Revision Stem is intended for use in fractures of the femur where a long section of bone is damaged and the stem must anchor into the distal half of the femur.

Contraindications: Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.

Performance data: Biomechanical Testing has been provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2000

Mr. Hartmut Loch
Chief Executive Officer
Plus Orthopedics
Building 15-100
3550 General Atomics Court
San Diego, California 92121-1122

Re: K994126
Trade Name: Modular-Plus® Revision Stem
Regulatory Class: II
Product Code: LWJ
Dated: March 3, 2000
Received: March 3, 2000

Dear Mr. Loch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/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

K994125 Supplemental Information # 1
MODULAR-PLUS® Revision Stem
March 4, 2000

510(k) Number (if known): K994126

Device Name: MODULAR-PLUS® Revision Stem

Indications for Use:

The MODULAR-PLUS® Revision Stem is intended for cementless use in fractures of the femur where a long section of bone is damaged and the stem must anchor into the distal half of the femur.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994126

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use No.

(Optional Format 1-2-96)