K024134 page 1 of 1

510(k) Summary

Date
December 13, 2002

JAN 15 2003

Submitter
PLUS Orthopedics
6055 Lusk Blvd
San Diego, CA 92121-2700

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-4694

Common name
Press-fit hip stem

Classification name
Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous uncemented (per 21 CFR section)

Equivalent Device
SL-PLUS Stem cleared on K001942.

Device Description
This stem has a flat rectangular cross sectional geometry that is intended to withstand rotational stress. The large proximal surfaces transmits stress to the greater trochanter and the arch of the calcar. This geometry achieves high primary stability and lays the foundation for good secondary stability.

This cementless stem is manufactured from titanium alloy (Ti6Al4V per ASTM F136) and the body surface is blasted with corrundum media. It is available in twelve stem sizes and has a 12/14 neck taper to accept 22, 28 or 32mm metal or ceramic heads.

Intended Use
The UNI Hip Stem is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head has been subject to disease or trauma. It is also intended to previously failed hip arthroplasties. This device is intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

Summary of Technological Characteristics Compared to Predicate Device
The UNI Stem is similar to the SL-PLUS Stem. Both stems have the same overall stem profile and are manufactured from similar titanium alloys (Ti6Al4V – UNI Stem & Ti6Al7Nb – SL-PLUS Stem). The indications for use are the same for both stems. The only difference are the minor change in material, removal of lateral suture holes from the SL-PLUS stem, and slightly smaller cross section and head offset for the Uni stem.

Summary Nonclinical Tests
Fatigue testing per ISO 7206-4 was successfully performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2003

PLUS Orthopedics
C/o Mr. J. D. Webb
1001 Oakwood Boulevard
Round Rock, TX 78681

Re: K024134
Trade/Device Name: UNI Hip Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LWJ, JDI
Dated: December 13, 2002
Received: December 16, 2002

Dear Mr. Webb:

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.

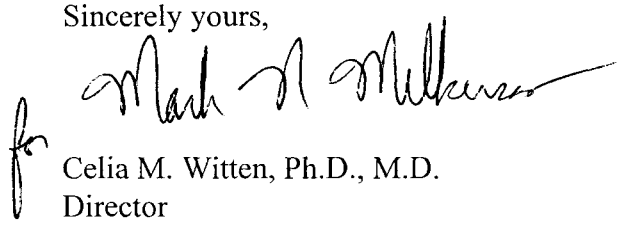
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 may be obtained 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 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): K024134

Device Name: UNI Hip Stem

Indications for Use:

UNI Hip Stem
Indications for Use

The UNI Hip Stem is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head has been subject to disease or trauma. It is also intended to treat previously failed hip arthroplasties. This device is intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

for Mark N Milkerson

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

510(k) Number K 024134