510(k) Summary

K032052
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Date
June 27, 2003

JUL 25 2003

Submitter
PLUS Orthopedics
6055 Lusk Blvd
San Diego, CA 92121

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade name
UC-PLUS Solution Unicondylar Knee

Common name
Unicondylar Knee

Classification name
Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/Polymer

888.3530 (per 21 CFR section)

Indications for Use
The UC-PLUS Solution Unicondylar Knee is intended for use in uni-compartmental degenerative arthritis, local osteonecrosis of the femoral condyle, light to medium uni-compartmental destruction of the knee joint due to idiopathic and post-traumatic degenerative arthritis, traumatic uni-compartmental bone and/or cartilage lesions. It is intended for use with bone cement only.

Equivalent Device
This modified component is equivalent to the previously cleared UC-PLUS Solution Unicondylar Knee (K982859) in terms of indications, usage and materials.

Device Description
This knee system consists of a femoral component and tibial component. The femoral component is fabricated from cast CoCrMo alloy (ASTM F79) and is 4mm thick. Symmetrical, the femoral components can be used on right or left knees. Cement pockets are cast into the components to provide a minimum 1mm cement mantle. The femoral component is available in four sizes.

The tibial component is manufactured from ultra-high molecular weight polyethylene. A cemented metal backed tibial component is also available. Both tibial components are available in five sizes and four thicknesses.

The subject of this Special 510(k) submission is the modification to the implant/bone interface of the femoral component and the elimination of the smallest size femoral component.

Summary Nonclinical Tests
The change in fin height of the UC-PLUS Solution Unicondylar Knee femoral component resulted in no increased risks and decreased the stresses in the component due to fatigue loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

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

Re: K032052
Trade/Device Name: UC-PLUS Solution Unicondylar Knee
Regulation Numbers: 21 CFR 888.3530
Regulation Names: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: June 27, 2003
Received: July 2, 2003

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) 594-4659. 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. Milkerson

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): K032052

Device Name: UC-PLUS Solution Unicondylar Knee

Indications for Use:

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(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, Neurological and Restorative Devices

510(k) Number_____

Prescription Use ____
(per 21 CFR 801.109) OR Over-the-Counter Use ____

(Optional format 1-2-96) _____

for Mark N. Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032052