

NOV 13 1997

510(k) Summary of Safety and Effectiveness Information

(as required by 807.92c), prepared by Hartmut Loch, President of
HHL Consulting for PLUS Orthopedics in San Diego, California
August 14, 1997

Trade name: PLUS-FIT Acetabular Cup

Common name: Cementless Total Hip Prosthesis, Acetabular Component

Classification name: Hip joint metal/polymer/metal semi constrained porous coated uncemented prosthesis

Equivalence: We are claiming substantial equivalency to the cementless RIMFIX Cup, marketed by Surgical Implants, Inc., Sarasota, Florida (K-Number unknown).

Characteristics: The PLUS-FIT Acetabular Cup is a cementless acetabular cup, which was designed with a triple-radius profile. The advantages are 1) minimal bone resection, 2) press-fit with physiological load transfer through the peripheral zone of the acetabulum, thus ensuring good primary stability without the need for screw fixation and 3) optimal osseous integration due to good primary stability.

Indications: The PLUS-FIT Acetabular Cup is intended for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions. In normal cases, however, the surgeon will use an acetabular implant one size larger and in exceptional cases two sizes larger.

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 laboratory tests were performed comparing cups of other leading manufacturers to the PLUS-FIT Acetabular Cup. All tests showed that the PLUS-FIT Acetabular Cup was comparable to, or exceeded, cementless competitive acetabular cups.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1997

Mr. Hartmut Loch
•President
HHL Consulting
Representing Plus Orthopedics
835 Cortez Lane
Foster City, California 94404

Re: K973077
Trade Name: PLUS-FIT Acetabular Cup
Regulatory Class: II
Product Code: LWJ
Dated: October 24, 1997
Received: October 27, 1997

Dear Mr. Loch:

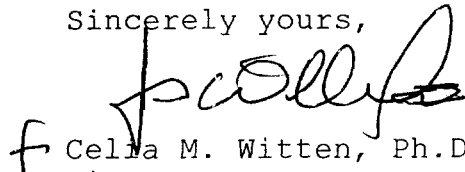
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 (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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


f Cella M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K973077

Page 1 of 1

510(k) Number (if known): AUG 18 12 21 PM '97 K973077

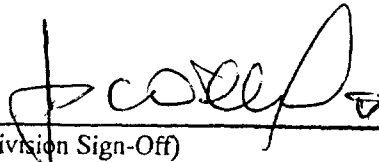
Device Name: PLUS-FIT ACETABULAR CUP

Indications for Use:

The PLUS-FIT Acetabular Cup is intended for all types of arthrosis, such as advanced destruction of the hip joint due to degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, sequelae of previous operations, such as internal fixation, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement. The same considerations apply to acetabular revisions. In normal cases, however, the surgeon will use an acetabular implant one size larger and in exceptional cases two sizes larger.

(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 K973077

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)