APR 6 2000

K992154

510(k) Summary of Safety and Effectiveness

(revised March 30, 2000)

submitted by
Hartmut Loch, C.E.O.
PLUS ORTHOPEDICS
3550 General Atomics Ct., Bldg. 15-100
San Diego, CA 92121

Trade name: BICON-PLUS Acetabular Components

Common name: Acetabular Cup System

Classification name: Prosthesis, hip, semi-constrained, metal/polymer, porous, uncemented 21 CFR 888.3358 (87 LPH)

Equivalence: OMNIFIT Threaded Acetabular Cup, K-883921, S/E 10/13/88

Characteristics: The BICON-PLUS Acetabular Components consists of threaded double cone made out of titanium with a polyethylene insert. Since the double cone corresponds very closely to the anatomical form of the acetabulum, the degree of bone resection in the region of the acetabulum base can be reduced. Two new titanium shells are available: The BICON-PLUS STANDARD cup and the BICON-PLUS POROSE cup. The size, thickness and height of the teeth have been adapted to the size of the cup. In addition to the standard insert, the new hooded version offers an increased support against luxation without compromising the range of motion. The titanium shells come in a range of nine standard sizes (sizes 1-9) and two special sizes (sizes 0 and 01). The PE inserts come in a range of sizes to match the shells to accommodate three ball head diameters (22mm, 28mm, and 32mm).

Indications: The BICON-PLUS Acetabular Components are intended for use in primary and revision total hip arthroplasty where the acetabular socket needs restructuring.

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. All test results are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2000

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

Re: K992154
Trade Name: Bicon-Plus Acetabular Components
Regulatory Class: II
Product Code: LPH
Dated: January 13, 2000
Received: January 14, 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,

Donna R. Bachner

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

Enclosure

510(k) Number (if known): K992154

Device Name: BICON-PLUS Acetabular Components

Indications for Use:

The BICON-PLUS Acetabular Components are intended for use in primary and revision total hip arthroplasty where the acetabular socket needs restructuring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992154

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

(Optional Format 1-2-96)