K003666

FEB - 8 2001

## 510(k) SUMMARY

Date: 11/27/00

Applicant's name: Corin USA
10500 University Center Drive, Suite 190
Tampa, FL 33612

Phone: (813) 977-4469
Fax: (813) 979-0042

Contact person: Joel Batts, Regulatory Affairs Manager

Summary
The purpose of this premarket notification submission is to gain clearance to market cobalt-chrome modular femoral heads and zirconia ceramic modular femoral heads with the previously approved Taper-Fit Total Hip System (K992234).

Substantial equivalence (SE) is claimed, herein, to the Taper-Fit Hip System as it was previously approved for use with stainless steel modular femoral heads.

The Taper-Fit Total Hip System is a total hip replacement system comprised of three types of components - femoral stems, modular femoral heads and distal stem centralizers. When used with modular ceramic femoral heads the "Hip joint, metal/ceramic/polymer, semi-constrained cemented prosthesis" classification applies. When used with cobalt-chrome or stainless steel modular femoral heads the "Hip joint, metal/polymer, semi-constrained cemented prosthesis" classification applies.

The femoral stem is manufactured from stainless steel in accordance with BS 7252 Part 9 [ISO 5832-9] – "Specifications for High Nitrogen Stainless Steel" and is provided with a polymethylmethacrylate stem centralizer. The stem is double tapered, collarless and highly polished.

The zirconia ceramic femoral heads are manufactured from high purity 3 mol% Yttria Stabilized Zirconia Polycrystals (Y-TZP).

Cobalt-chrome femoral heads are manufactured from cast cobalt-chromium alloy to BS 7252 Part 4 [ISO 5832-4].

All femoral head types, by material, are available in short, standard and long neck sizes. The 12/14 bore on each head is designed to fit a 12/14 stem cone.

The system is indicated for the relief of pain and restoration of hip function following the effects of osteo, rheumatoid and inflammatory arthritis, post-traumatic disease effects, avascular necrosis and total hip revision.

*The sole difference between the device as submitted in the current submission and the predicate device is the femoral head material.* The predicate device was approved for use with a stainless steel femoral head.

Pursuant to the comments of the FDA/Orthopedic Device Branch (see facsimile in Section 2), the applicant has carried out bench testing in order to demonstrate SE to the predicate device. The results of this testing are located in Sections 8 and 9. As can be seen in Section 4 of the present submission, we claim SE to the predicate device based on identical femoral stem and head geometries/dimensions, in addition to, similar compatibilities of the femoral stem and modular femoral head materials as demonstrated in the test results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2001

Mr. Joel K. Batts
Regulatory Affairs Manager
Corin USA
10500 University Center Drive, Suite 190
Tampa, Florida 33612

Re: K003666
Trade Name: Taper-Fit Total Hip System
Regulatory Class: II
Product Code: JDI, LZO
Dated: November 27, 2000
Received: November 28, 2000

Dear Mr. Batts:

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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhem

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): K003666

DEVICE NAME: Taper-Fit Total Hip System

INDICATIONS FOR USE:

Taper-Fit Total Hip System is indicated for the relief of pain and restoration of hip function following the effects of osteo, rheumatoid and inflammatory arthritis, post-traumatic disease effects, avascular necrosis and total hip revision.

for Mark N Milhous

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

510(k) Number K003666

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)