

K97 3595
510(k) SUMMARY

DEC 19 1997

Name of Company: Corin Medical Ltd
The Corinium Centre
Cirencester
Gloucestershire
GL7 1YJ
England

Name of Device: Posterior Stabilised Nuffield Total Knee System

Device Description: The Posterior Stabilised Total Knee Replacement System is a line extension of the previously cleared Nuffield Total Knee System which has been on the market since 1989.

The device is used to restore knee function in patients with degenerative rheumatoid or osteoarthritis in cases where the degenerative process has led to non or inadequate function of the posterior cruciate ligament.

The device incorporates cobalt-chrome alloy femoral and tibial components and a UHMWPE tibial insert. Alternatively, an all-polyethylene tibial component may be implanted.

SUMMARY OF SUBSTANTIAL EQUIVALENCE AND SAFETY AND EFFECTIVENESS

The Posterior Stabilised Nuffield Total Knee System is substantially equivalent to both the Insall Burstein II Knee System promoted by Zimmer in the USA since 1987 and the Nuffield Total Knee System promoted by Corin Medical since 1989. The reasons for this are summarised below.

- a) All are three part knees utilising cobalt-chrome alloy femoral and tibial components and a UHMWPE tibial insert.
- b) All three have a range of sizes of components and thicknesses of polyethylene inserts.
- c) All are designed for cemented use only.
- d) All contain within the range an all-polyethylene monoblock tibial component for low demand patients.

This submission is supported by extensive mechanical test data confirming the devices' safety and effectiveness. The Posterior Stabilised Nuffield Total Knee System has been in clinical use outside the United States for eight years and no significant post-operative problems have been reported.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 1997

Mr. Craig Corrance
President
Corin U.S.A.
10500 University Center Drive, Suite 130
Tampa, Florida 33612

Re: K973595
Trade Name: Posterior Stabilised
Nuffield Total Knee System
Regulatory Class: II
Product Code: JWH
Dated: September 4, 1997
Received: September 22, 1997

Dear Mr. Corrance:

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.

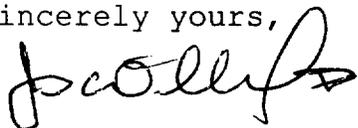
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 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): K97-3595

Device Name: The Posterior Stabilised Nuffield Total Knee System

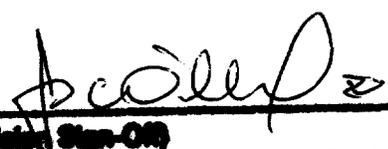
INDICATIONS FOR USE

Relief of pain and restoration of knee function following the effects of osteo, rheumatoid and inflammatory arthritis, post-trauma disease effects, avascular necrosis, and total knee revision with or without varus, valgus or flexion deformity.

The tibial and femoral components are intended for use with bone cement.

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

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973595

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____