

APR 29 1998

K980545

510(k) SUMMARY

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

Name of Device: The Nuffield Total Knee System

Device Description: The devices which are the subject of this submission constitute a line extension to the previously cleared Nuffield Total Knee System which has been on the market since 1989.

This submission addresses those Nuffield Total Knee System devices which are plasma sprayed.

The devices restore knee function in patients with degenerative rheumatoid or osteoarthritis, and are suitable for primary arthroplasty or revision surgery.

The plasma coated devices which are the subject of this submission are:

- i. NTK Femurs (stemmed, stem-less and pegged)
- ii. NTK Tibias (stemmed)
- iii. Patellas

These devices are used in conjunction with previously cleared NTK devices, ie UHMWPE Tibial Inserts, all-UHMWPE Tibias and Patellas.

The devices which are the subject of this submission are manufactured from cobalt-chrome alloy and are plasma sprayed; the plasma coating provides an increased surface roughness to act as a key for mechanical interlock with PMMA Bone Cement.

Although the Nuffield Total Knee is designed to spare the posterior cruciate ligament, the stability of the replacement relies on neither the anterior nor posterior cruciate ligament and the devices can be used when both ligaments are absent.

The Plasma Coated Nuffield Total Knee System is intended for use ONLY with bone cement.

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SUMMARY OF SUBSTANTIAL EQUIVALENCE AND SAFETY AND EFFECTIVENESS

The Plasma Coated Nuffield Total Knee System is substantially equivalent to both the Duracon Knee System, promoted by Howmedica in the US since 1993, and the Nuffield Total Knee System, promoted in the US by Corin Medical since 1993. The reasons for this are summarised below:

- a. All are four-part knees utilising cobalt chrome alloy femoral and tibial components, ultra high molecular weight polyethylene tibial inserts and metal-backed and all-polyethylene patella components.
- b. All components have a range of sizes and differing thicknesses of polyethylene.
- 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 Plasma Coated Nuffield Total Knee System has been in clinical use outside the United States for eight years and no post-operative problems have been reported.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Craig Corrance
President
Corin U.S.A.
10500 University Center Drive
Suite 190
Tampa, Florida 33612

Re: K980545
The Nuffield Total Knee System (Ti Plasma Spray)
Regulatory Class: II
Product Code: JWH
Dated: February 2, 1998
Received: February 12, 1998

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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.
3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

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The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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.

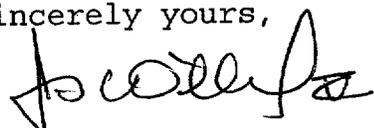
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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): K980545

Device Name: The 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.

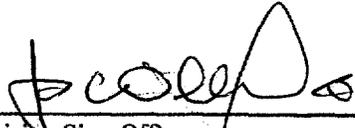
The tibial and femoral components are intended for use only with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation

Prescription Use f
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980345