K050764

AUG 2 4 2005

510(k) SUMMARY

Date: 3/1/05

Applicant Name: Corin Group PLC
The Corinium Centre
Cirencester
Gloucestershire
GL7 1YJ
United Kingdom

Contact Person: Richard Sharp
Regulatory Affairs Director
Corin Group PLC
+44 1285 659866

Proprietary Name: Uniglide™ Unicondylar Knee Replacement System

Common Name: Unicompartmental knee replacement

Classification Name: Prosthesis, knee, femerotibial, semi-constrained, cemented, metal/polymer (21 CFR 888.3530)

Class/Product Code: Class II / HRY

Substantially Equivalent Devices: Vanguard M™ Series Unicondylar Tibial Bearings (K042093); Repicci II™ Unicondylar Knee (K980665); Link Endo-Model™ Sled Uni-knee (K954186); UC Plus Solution Unicondylar Knee System (K982859)

Device Description: The device consists of Cobalt Chrome (CoCr) alloy femoral component which articulates against an ultra high molecular polyethylene (UHMWPE) tibial component.

Indications for Use: Replacement of the articulating surfaces of one tibio-femoral compartment of the knee where this has been affected by primary degenerative disease, post traumatic degenerative disease or damage due to previous surgical intervention and the anterior and posterior cruciate ligaments are present and functionally intact. The device is indicated for use in the medial or lateral compartment of the knee and is intended to be used with bone cement.

Basis for Substantial Equivalence: The sponsor claims substantial equivalence (SE) of the Uniglide Unicondylar Knee Replacement System to the previously approved Vanguard M series, Recippi II, Link Endo-Model Sled and UC Plus Solution unicondylar knees (see Table 1).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2005

Mr. Joel K. Batts
Director, US Regulatory Affairs
Corin U.S.A.
10500 University Center Drive
Suite 190
Tampa, Florida 33612

Re: K050764
Trade/Device Name: Uniglide Unicondylar Knee Replacement System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: August 03, 2005
Received: August 05, 2005

Dear Mr. Sharp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K050764

Device Name: Uniglide Unicondylar Knee Replacement System

Indications for Use:

The Uniglide unicondylar knee replacement system is indicated for use in the replacement of the articulating surfaces of one tibio-femoral compartment of the knee where this has been affected by primary degenerative disease, post traumatic degenerative disease or damage due to previous surgical intervention. The device is indicated in these cases where the degeneration is substantially limited to the compartment to be replaced and the anterior and posterior cruciate ligaments are present and functionally intact. The device is indicated for use in the medial or lateral compartment of the knee. The device is intended to be used with bone cement. The device is intended for prescription use only.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

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

510(k) Number K050764
Concurrence of CDRH, Office of Device Evaluation (ODE)