

K972995
510(k) SUMMARY

NOV 10 1997

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

Name of Device: C-Fit and DC-Fit Acetabular Cup System

Device Description: Acetabular Cup System for use with previously cleared femoral stems and modular heads.

The acetabular cups are available in a range of diameters and are plasma sprayed.

The devices are used to resurface the acetabulum and are used in combination with UHMWPE inserts, femoral stems and modular heads to reinstate function following the degenerative effects of osteo and rheumatoid arthritis, post-trauma disease effects, avascular necrosis and septic or aseptic total hip revision.

The acetabular cups are manufactured from cobalt chrome alloy. The cobalt chrome plasma spray coating provides an increased surface roughness to act as a key for mechanical interlock with PMMA bone cement.

Summary of substantial equivalence and safety and effectiveness

Corin claim that the range of C-Fit and DC-Fit Cups are substantially equivalent to the Mallory Head Acetabular Cup range which has been promoted in the USA by Biomet Inc since 1990. The reasons for this are summarised below.

- a) Both are modular cups manufactured from cobalt chrome alloy and utilise UHMWPE liners.
- b) Both are coated with a plasma spray of the same alloy.
- c) Both are designed for cemented use and for use with screws.
- d) Both are available in a range of sizes from 42mm - 70mm and can accommodate a range of femoral head sizes.

This submission is supported by extensive mechanical test data confirming the devices' safety and effectiveness. The plasma coated C-Fit and DC-Fit Acetabular Cups have been in clinical use outside the USA for ten years and two years respectively and no significant post-operative problems have been reported.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1997

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

Re: K972995
Trade Name: The C-Fit and DC-Fit Acetabular Cup System
Regulatory Class: II
Product Code: JDI
Dated: July 21, 1997
Received: August 12, 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.

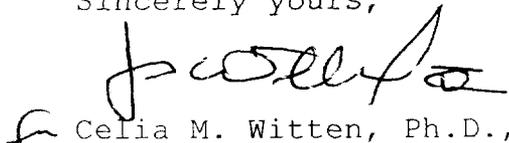
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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): K972995

Device Name: The C-Fit & DC-Fit Acetabular Cup System

INDICATIONS FOR USE

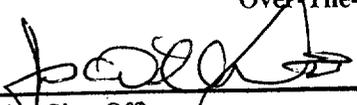
Relief of pain and restoration of hip function following the effects of osteo, rheumatoid and inflammatory arthritis, post-trauma disease effects, avascular necrosis, and total hip revision.

The C-Fit and DC-Fit plasma sprayed acetabular 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 X
(per 21 CFR 801.109)

OR Over-The-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972995