

§10(k) SUMMARY

K973005

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

NOV 10 1997

Name of Device: Corifix Ligament Anchor

Device Description: A Ligament Anchor system comprising a range of Ligament Anchors, Ligament Staples (Claws) and Bone Screws.

The devices are used in conjunction with the patient's medial hamstring tendons, namely semitendinosus and gracilis, by securing the looped tendons to the femur and tibia in order to repair damaged anterior and posterior cruciate ligaments.

A dedicated Ligament Claw Impactor is used during impaction of the Ligament Claw into the patient's femur.

Each of the implantable devices is manufactured from titanium which is certified to BS 7252 Part 3 (ISO 5832 Part 3)

Reconstruction of the anterior and posterior cruciate ligaments using the Corifix Ligament Anchor System allows immediate post-operative early joint motion and early weight bearing.

SUMMARY OF SUBSTANTIAL EQUIVALENCE AND SAFETY AND EFFECTIVENESS

The Corifix Ligament Anchor System is substantially equivalent to the (Linvatec) Concept 6.5mm Screw and Spiked Washer Anchoring Implant.

- a) Both implants are made of titanium.
- b) Both are used to anchor semitendinosus and gracilis grafts in place during ACL surgery.
- c) Both utilise 6.5mm titanium cancellous screws.
- d) Both have a spiked washer which accepts a 6.5mm diameter screw.

This submission is supported by mechanical test data and clinical results confirming the device's safety and effectiveness. The device has been in clinical use outside the USA for approximately four years and no significant post-operative problems have been reported.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

NOV 10 1997

Re: K973005
Trade Name: The Corifix Ligament Anchor
Regulatory Class: II
Product Code: HWC
Dated: August 6, 1997
Received: August 13, 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.

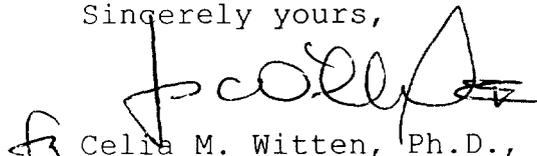
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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


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

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510(k) Number (if known): K973005

Device Name: The Corifix Ligament Anchor

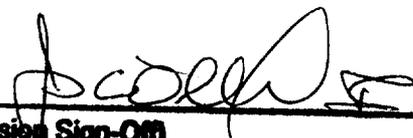
INDICATIONS FOR USE

For use in conjunction with the patient's medial hamstring tendons, namely semitendinosus and gracilis, by securing the looped tendons to the femur and tibia in order to repair damaged anterior and posterior cruciate ligaments.

Relief of pain and restoration of knee function arising from damage to anterior or posterior cruciate ligaments.

(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 K973005

Prescription Use
 (per 21 CFR 801.109)

OR

Over-The-Counter Use