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MAR - 6 2000

510(k) SUMMARY

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

Name of Device: **Ligament Anchor Soft Screw** .

Device Description:

The Corifix ligament Anchor is a headless, tapered, round threaded, cannulated screw manufactured from titanium alloy (6Al 4V) which conforms to BS 7252/3 and ASTM 136/96. The screw has a 3.5mm hex drive.

The Ligament Anchor Soft Screw has been on the foreign (i.e. non-US) market since January 1997, since that date approximately 1,700 screws have been implanted.

Intended Use.

The screws are used in anterior cruciate ligament and posterior cruciate ligament reconstruction using hamstrings. This device may also be used for bone patellar tendon bone fixation.

The soft screw provides solid fixation of the ligament without damaging grafts or the need for pre-tapping, thus avoiding damage to the hamstring grafts.

The ligament anchor soft screw can be used in both the femur and tibia or in conjunction with the Corifix Ligament Anchor which is already 510k approved. (K973005)

Material.

The material used for the Ligament Anchor Soft Screw is Titanium Alloy 6Al4V, certified to BS 7252:Pt. 3:1997 Metallic materials for surgical implants - Specification for wrought titanium 6-Aluminium 4-Vanadium alloy and ASTM F136-96 Wrought Titanium-6Aluminium-4Vanadium ELI.

Device Geometry.

The Corifix Ligament Anchor Soft Screw has a rounded thread to prevent damage to the graft, is cannulated and tapered to aid insertion, and has a 3.5mm hex drive.

Sizes

The Corifix Ligament Anchor Soft Screw is available in four diameters i.e 7mm, 8mm, 9mm & 10 mm, for each diameter of screw four lengths of screw are available i.e. 20mm, 25mm, 30mm, & 35 mm.

Summary of Mechanical Testing (Further details provided on Page 14 of this dossier).

The titanium alloy 6Al4V from which the Corifix Ligament Anchor Soft Screw is manufactured is tested and certified to BS 7252:Pt. 3:1997 Metallic Materials for Surgical Implant – Specification for wrought titanium 6-Aluminium 4-Vanadium alloy and ASTM F136-96 Wrought Titanium-6Aluminium-4Vanadium ELI.

Independent mechanical testing of the most popular sizes of screw determined that the maximum expected clinical loads applied to this device are 150N during walking and 450N during jogging. The fixation strength of the Corifix Ligament Anchor Soft Screw was found to be 691N.

Device to which Substantial Equivalence is Claimed and Device Specific Features

Substantial equivalence for the Corifix Ligament Anchor Soft Screw is claimed with the Smith & Nephew RCI Screw, which has been in clinical use within the USA for 5 years. (Predicate Device No. K947134).

The comparable features of the RCI Screw & Corifix Ligament Anchor Soft Screw are that both screws have a rounded thread, are cannulated, made of titanium alloy 6Al4V, have a 3.5mm hex. drive and are tapered to aid insertion. The advantage of the Corifix Ligament Anchor Soft Screw is that it is available in a range of sizes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2000

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

Re: K994152
Trade Name: Corafix Ligament Anchor Soft Screw
Regulatory Class: II
Product Code: HWC
Dated: November 18, 1999
Received: December 8, 1999

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 control provisions of the Act. The general control 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.

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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510k Number (of known): Prov. – K994152

Device Name :- Corifix Ligament Anchor Soft Screw.

INDICATIONS FOR USE

The Corifix Ligament Anchor Soft Screw is used for anterior and posterior cruciate ligament reconstruction using hamstrings.

This technique provides reduced soft-tissue morbidity and reduced post operative pain on kneeling whilst improving the cosmetic appearance for the patient.

The hamstring surgical technique and the Corifix Ligament Anchor Soft Screw work together for fixation of a hamstring tendon graft, without bone block, to achieve anatomic aperture fixation of the hamstring tendon graft in the tibia or femur.

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

Concurrence of CDRH, Office of Device Evaluation (ODE).

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994152

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)