510(k) SUMMARY

K97 3231

NOV 20 1997

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

Name of Device: Corifix Dynamic Hip Screw System

Device Description: The Dynamic Hip Screw System comprises stainless steel Dynamic Compression Plates and Compression Lag Screws and optional Hexagonal Screw for use in the fixation of femoral neck fractures.

The devices provide support to the femur and femoral head during the natural process of bone regeneration to repair the femoral neck fracture. The devices are designed to withstand the *in vivo* loads experienced during normal activity throughout the life of the implant.

A dedicated Corifix Dynamic Hip Screw instrument set is used to implant the devices or Stratetc (Synthes) instruments may be used.

Each of the implantable devices is manufactured form stainless steel which in certified to BS 7252 Part 1.

SUMMARY OF SUBSTANTIAL EQUIVALENCE AND SAFETY AND EFFECTIVENESS

The Corifix Dynamic Hip Screw System is substantially equivalent to the Stratec (Synthes) DHS System for the following reasons:

a) Both are manufactured from 316 LVM stainless steel.

b) Both have a similar range of plate angles and holes.

c) Both are designed to be used to treat proximal hip fractures.

d) Both of the plates are the same thickness and width.

e) Both have the same outside barrel diameter.

This type of device has been in clinical use for over twenty years and no significant problems have been reported.

The Corifix Hip Screw has been in clinical use outside the USA for three years and no post-operative problems have been reported.

The Corifix product design is generic and equivalent to the Synthes DHS System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 1997

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

Re: K973231
Trade Name: Corifix Dynamic Hip Screw
Regulatory Class: II
Product Code: KTT
Dated: August 12, 1997
Received: August 27, 1997

Dear Mr. Corrance:

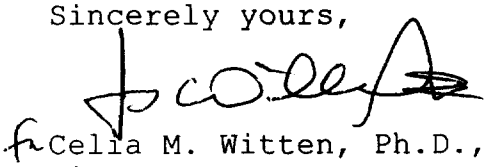
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for 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): _____

Device Name: **The Corifix Dynamic Hip Screw System**

INDICATIONS FOR USE

The Dynamic Hip Screw System devices are used in the treatment of femoral neck fractures in the pertrochanteric, intertrochanteric and high subtrochanteric regions of the femur, or in the treatment of combinations of these fractures.

Pertrochanteric fractures occur from the greater to lesser trochanter. Intertrochanteric fractures occur within the trochanteric area. High subtrochanteric fractures occur immediately below the trochanter.

The devices provide support to the femur and femoral head during the natural process of bone regeneration to repair the femoral fracture.

The devices are designed to withstand the *in vivo* loads experienced during normal activity throughout the life of the implant.

(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 K973231

Prescription Use X **OR** **Over-The-Counter Use** ____
(per 21 CFR 801.109)