

SEP 14 1998



WRIGHT

MEDICAL TECHNOLOGY, INC.

5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

K982390

510(k) SUMMARY

Contact Person: Lynne Witkowski
Date Prepared: July 7, 1998

Trade Name: CONCISE™ Compression Hip Screw System (Sterile)
Common Name: Metallic Bone Fixation Device
Classification: II
Predicate Device: CONCISE Compression Hip Screw System (Non-Sterile)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Description/Intended Use

The CONCISE™ Compression Hip Screw System (Sterile) consists of lag screws, cortical bone screws, compression screws, and compression bone plates. Each component is available in a range of sizes to fit varying anatomical requirements.

The CONCISE™ Compression Hip Screw System (Sterile) is indicated for use in stable and unstable fractures in which a stable medial buttress can be reconstructed for fractures of the proximal femur including:

- intertrochanteric fractures
- subtrochanteric fractures
- basilar neck fractures
- selected non-unions

Materials

All component are manufactured from 316 LVM stainless steel conforming to ASTM F 138.

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SEP 14 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lynne Witkowski
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K982390
Trade Name: CONCISE™ Compression Hip
Screw System (Sterile)
Regulatory Class: II
Product Code: KTW
Dated: July 7, 1998
Received: July 9, 1998

Dear Ms. Witkowski:

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.

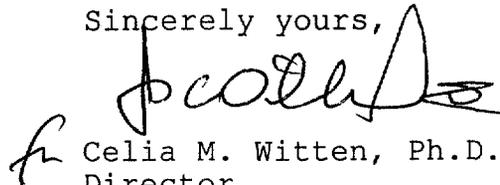
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



h 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) SUBMISSION
WRIGHT MEDICAL TECHNOLOGY, INC.
CONCISE™ Compression Hip Screw System (Sterile)

C. Indications for Use of the Device

510(k) Number (if known): K982390

Device Name: CONCISE™ Compression Hip Screw System (Sterile)

Indications for Use:

The CONCISE™ Compression Hip Screw System is indicated for stable and unstable fractures in which a stable medial buttress can be reconstructed for fractures of the proximal femur including:

- Intertrochanteric fractures
- Subtrochanteric fractures
- Basilar neck fractures
- Selected trochanteric non-unions

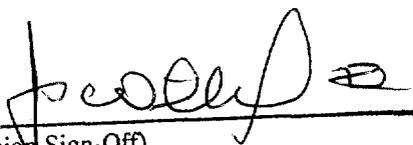
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Or Over-the-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982390

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