K994061

FEB 14 2000

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

510K Summary

Company: Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002
Date: November 30, 1999
Trade Name: LoCon-T™ Distal Radial Plate System
Common Name: Metallic Bone Fixation System
Predicate Device: Zimmer Forte Distal Radial Plate System

Description/Intended Use:
The LoCon-T Distal Radial Plate System includes four side specific dorsal plate, one volar T-plate, a dorsal plate extender, cortical screws, cancellous screws, and buttress pins. The plates and plate extender are manufactured from Stainless Steel (ASTM F 139). The screws are manufactured from Stainless Steel (ASTM F 138). The pins are manufactured from Stainless Steel (ASTM F 1314). The plates, pins, extender, and screws are designed to be lower in profile and secure bone fragments. The dorsal plates are available in two sizes for both right and left configurations. The cancellous screws are available in partially and fully threaded 4.0mm diameter designs ranging in length from 10.0 to 40.0mm in 2.0mm increments. The cortical screws are available in 3 diameters. The pins are 1.8mm in diameter and range in length from 12mm to 30mm.

Intended Use:
Use of the LoCon-T Distal Radial Plate System is intended to be used for fixation of unstable distal radius fractures in which closed reduction is not suitable:

- Joint destruction and/or subluxation visible on x-ray;
- Failed fracture fixation with or without bone graft;
- Osteotomy and repair of distal radius malunion with or without bone graft;
- Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone;
- Dorsal plates are indicated for use with comminuted articular fractures, shearing fractures of the articular surface, severely comminuted extra-articular fractures, and fractures in which reduction has been lost following fixation with percutaneous pins with or without an external fixator; or
- T-plates are indicated for use with volar articular shearing fractures

Testing Summary:
The LoCon-T Distal Radial Plate System was declared substantially equivalent to the predicate devices. Mechanical test data demonstrated that the material and subject device design meets the strength requirements of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2000

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

Re: K994061
Trade Name: LoCon-T™ Distal Radial Plate System
Regulatory Class: II
Product Code: HRS
Dated: November 30, 1999
Received: December 1, 1999

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.

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) 594-4595. 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,

Neil R P Ogden for

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

Enclosure

Indications for Use Statement

510(k) Number (if known) K994061

Device Name **LoCon-T Distal Radial Plate System**

Indications for Use

Intended Use

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- Joint destruction and/or subluxation visible on x-ray;
- Failed fracture fixation with or without bone graft;
- Osteotomy and repair of distal radius malunion with or without bone graft;
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- T-plates are indicated for use with volar articular shearing fractures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRO for JSD

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K994061

Prescription Use X OR Over-The Counter Use ____

(per 21 CFR 801.109)