OCT 7 - 2004 K 042358

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the LOCON™ VLS Distal Radius Plate.

Submitted By:	Wright Medical Technology, Inc.
Date:	August 30, 2004
Contact Person:	Jeanine H. Redden
	Regulatory Affairs Specialist II
Proprietary Name:	**LOCON™ VLS Distal Radius Plate**
Common Name:	Volar Plate
Classification Name and Reference:	21 CFR 888.3030 Plate, Fixation, Bone – Class II
Device Product Code and Panel Code:	21 CFR 888.3030 Plate, Fixation, Bone – Class II

DEVICE INFORMATION

A. INTENDED USE

The LOCON™ VLS Distal Radius Plate is intended to be used for fixation of unstable distal radial 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;
- Volar 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;
- Locking volar plates are indicated for use with volar articular shearing fractures

B. DEVICE DESCRIPTION

The LOCON™ VLS Distal Radius Plate System consists of plates, cortical screws, and cancellous screws. The design features of the plates and screw components are summarized below:

Plates

- Manufactured from stainless steel
- Offered in two lengths: Standard and Long
- Left and right configurations
- Locking and non-locking screw holes in distal portion
- Cortical screw holes located in proximal portion
- Compression slot feature in proximal portion
- K-wire holes in head and shaft
- Cupped head with varying arch to accommodate patient's anatomy

Cortical Screws

- Manufactured from stainless steel
- Available with 3.5mm diameter in lengths from 12mm- 20mm

Cancellous Screws

- Manufactured from stainless steel
- Available in two designs: standard and locking
- Standard screws are available with 2.7mm diameter in lengths from 12 - 26mm in 2mm increments
- Locking screws are available with 2.7mm diameter in lengths from 14 - 26mm in 2mm increments

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the LOCON™ VLS Distal Radius Plate System are substantially equivalent to the LOCON-T® Distal Radial Plate System. The fundamental scientific technology of the modified device has not changed relative to the predicate device. The safety and effectiveness of the LOCON™ VLS Distal Radius Plate is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Jeanine H. Redden
Regulatory Affairs Specialist II
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K042358
Trade/Device Name: LOCON™ VLS Distal Radius Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: August 30, 2004
Received: September 13, 2004

Dear Ms. Redden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: LOCON™ VLS Distal Radius Plate

Indications For Use:

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- Locking volar plates are indicated for use with volar articular shearing fractures

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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