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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 EVOLVE® Radial Plate.

Submitted By:	Wright Medical Technology, Inc.
Date:	October 28, 2003
Contact Person:	Katie Logerot
	Regulatory Affairs Associate
Proprietary Name:	EVOLVE® Radial Plate
Common Name:	Radial 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 EVOLVE® Radial Plate is indicated for fixation of unstable radius fractures in which closed reduction is not suitable.

B. DEVICE DESCRIPTION

The EVOLVE® Radial Plate system consists of plates, cortical screws, and locking screws. The design features of the plates and locking screws of the EVOLVE® Radial Plate system are summarized below:

Plates

- Manufactured from stainless steel
- Offered in two lengths: Short and Long
- Cupped head with varying arch to accommodate patient's anatomy
- Compression slots compress fracture as screw is tightened to facilitate uniting a fracture
- Threaded screw holes in the head portion accept locking screws for stable plate/screw construct
- Cortical screw holes located in head and shaft

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011.39.0250.678.227 Italy **011.81.3.3538.0474** Japan **011.44.1483.721.404** UK

Cortical Screws

- Manufactured from stainless steel
- Available in two diameters: 2.7mm and 1.8mm in varying lengths ranging from 3.0mm to 40.0mm in 2mm increments
- Identical to cortical screws previously submitted and cleared under the I.OCON-T® Distal Radial Plating System

Locking Screws

- Manufactured from stainless steel
- Available in lengths from 14mm to 28mm in 2mm increments
- Threads on the screw mate to threads in the screw holes to fix the screw to the plate reducing the likelihood of screw loosening and improving the screw to plate stability of the system

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the EVOLVE® Radial Head Plate are substantially equivalent to previously cleared plating systems. The safety and effectiveness of the EVOLVE® Radial Head Plate are 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

JAN 2 8 2004

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

Re: K033456
Trade/Device Name: EVOLVE Radial Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: October 28, 2003
Received: October 30, 2003

Dear Ms. Logerot:

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 Celia M. Witten, Ph.D., M.D.
Division 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): K033456

Device Name: EVOLVE® Head Plate

Indications For Use:

The EVOLVE® Radial Plate is indicated for fixation of unstable radius fractures in which closed reduction is not suitable.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 of General, Restorative and Neurological Devices

K033456