JUL 30 2008

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the S Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves a Summary of Safety and Effectiveness for the use of the EVOLVE® EPS System.

Submitted By:	Wright Medical Technology, Inc.
Date:	April 23, 2008
Contact Person:	Theresa Leister
	Senior Regulatory Affairs Specialist
Proprietary Name:	**EVOLVE® EPS System**
Common Name:	Bone Plate System
Classification Name and Reference:	21 CFR 888.3030 Plate, Fixation, Bone – Class II
Device Product Code and Panel Code:	Orthopedics/87/HRS

DEVICE INFORMATION

A. INTENDED USE

The EVOLVE® EPS System is intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia and fibula.

B. DEVICE DESCRIPTION

The design features of the EVOLVE® EPS System are described below.

- Consists of a variety of pre-contoured plate geometries
- Plates feature compression slots and locking screw holes
- Manufactured from Stainless Steel
- Screws are available in both locking and non-locking designs
- Screws are available in 2 diameters and 18 lengths

The design features of the EVOLVE® EPS System are substantially equivalent to the desig features of other devices previously cleared for market.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the EVOLVE® EPS System substantially equivalent to previously cleared predicate devices. The safety effectiveness of the EVOVE® EPS System is adequately supported by the substan equivalence information, materials information, and analysis data provided within Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Wright Medical Technology, Inc.
% Ms. Theresa Leister
5677 Airline Road
Arlington, TN 38002

JUL 30 2008

Re: K081373
Trade/Device Name: Evolve EPS System
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: May 14, 2008
Received: May 16, 2008

Dear Ms. Leister:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081373

Indications for Use

510(k) Number (if known): K081373

Device Name: EVOLVE® EPS System

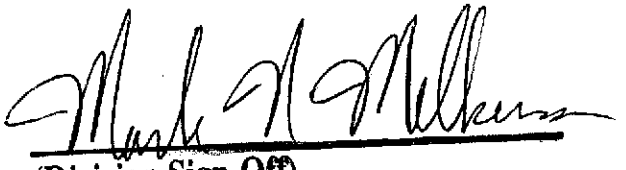
Indications For Use:

The EVOLVE® EPS System is intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia and fibula.

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)



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

510(k) Number K081373