K100146 (1/1)

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

FEB - 2 2010

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® EPS ORTHOLOC™ System.

Submitted By:	Wright Medical Technology, Inc.
Date:	January 11, 2010
Contact Person:	Kelsey Lee Regulatory Affairs Specialist
Proprietary Name:	**EVOLVE® EPS ORTHOLOC™**
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 ORTHOLOC™ System is intended for fixation of fractures, osteotomies and nonunions of the olecranon, humerus, radius, ulna.

B. DEVICE DESCRIPTION

The EVOLVE® EPS ORTHOLOC™ System consists of plates manufactured per ASTM F138 or F139 and screws manufactured per ASTM F138 or F2229. The plates are pre-contoured with compression slots and locking screw holes. The screws will be available in both locking and non-locking designs.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features of the EVOLVE® EPS ORTHOLOC™ System are substantially equivalent to the design features of the predicates identified in this 510(k) submission. The safety and effectiveness of the EVOLVE® EPS ORTHOLOC™ System are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
% Ms. Kelsey Lee
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

FEB - 2 2010

Re: K100146
Trade/Device Name: Evolve® EPS ORTHOLOC™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: January 11, 2010
Received: January 19, 2010

Dear Ms. Lee:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

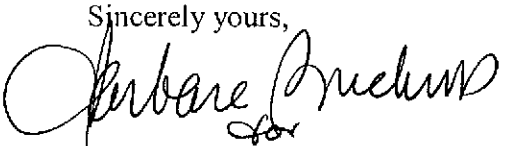
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K100146

Device Name: EVOLVE® EPS ORTHOLOC™ System

Indications For Use:

The EVOLVE® EPS ORTHOLOC™ System is intended for fixation of fractures, osteotomies and nonunions of the olecranon, humerus, radius, ulna.

Prescription Use __xxx__ 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100146