K112772(1/2)

WRIGHT.

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

OCT - 7 2011

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 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the ORTHOLOC™ Bone Screws.

A.1. Submitted By: Wright Medical Technology, Inc.
5677 Airline Rd
Arlington, TN 38002

Date: August 29, 2011

Contact Person: Kellen Hills

Regulatory Affairs Specialist

(901) 290-5816

A.2. Proprietary Name: **ORTHOLOC™ Bone Screws**

Common Name: Bone Screw

Device Classification Regulation: 21 CFR 888.3040—Class II

Device Product Code & Panel: HWC: Screw, Fixation Bone

87 Orthopedics

A.3. Predicate Device: K102429—ORTHOLOC™ 3Di Ankle Plating System and ORTHOLOC™ Bone Screws

K082320—Wright™ Compression Screws

A.4. Device Description

The ORTHOLOC™ Bone Screws subject to this premarket notification include the non-locking 3.5mm low profile cortical bone screws and non-locking 3.5 and 4.0 cortical bone screws.
These screws are manufactured from titanium alloy and have a solid core. The implants are single use only devices.

A.5. Intended Use

ORTHOLOC™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

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A.6. Technological Characteristics Comparison

The subject ORTHOLOC™ Bone Screws are identical to the predicate ORTHOLOC™ Bone Screws with the exception of the radii at the transition from the screw head to the screw shaft. This change resulted in approximately one thread being removed from the distal portion of the screw.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence is shown through worst-case pull out testing, materials information, and comparison of design characteristics. The results show that the subject ORTHOLOC™ Bone Screws can be expected to perform at least as well as the legally marketed predicate ORTHOLOC™ Bone Screws and Wright Compression Screws.

B.2. Substantial Equivalence – Clinical Evidence

N/A

B.3. Substantial Equivalence - Conclusions

Substantial equivalence is shown through worst-case pull out testing, materials information, and comparison of design characteristics. The subject screws are identical in indication for use, diameter, size range and material to the predicates, and differ only in screw neck radii. No new types of safety and effectiveness questions can be expected. From the evidence given in the Premarket Notification, the subject devices can be expected to perform at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc
% Kellen Hill
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

OCT - 7 2011

Re: K112772
Trade/Device Name: ORTHOLOC™ Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 12, 2011
Received: September 23, 2011

Dear Kellen Hill:

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 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

K112772(1/1)

Indications for Use

510(k) Number (if known):

Device Name: ORTHOLOC™ Bone Screws

Indications For Use:

ORTHOLOC™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

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)

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

510(k) Number K112772