Wright Medical Technology, Inc.
5677 Airline Road Arlington, TN 38002
www.wmt.com

510(K) SUMMARY

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 CHARLOTTE™ Snap-Off Screw.

1. **Submitted By:**	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	March 5, 2014
Contact Person:	Leslie Fitch Senior Regulatory Affairs Specialist (901) 867-4120
2. **Proprietary Name:**	CHARLOTTE™ Snap-Off Screw
Common Name:	Smooth or threaded metallic bone fixation fastener
Classification Name and Reference:	21 CFR 888.3040 – Class II
Device Product Code, Device Panel:	HWC: Orthopedic
3. **Predicate Devices:**	K043583 – CHARLOTTE™ Snap-Off Screw K050819 – CHARLOTTE™ Snap-Off Screw

4. Device Description

The CHARLOTTE™ Snap-Off screw is a cortical bone screw intended to aid in achieving fixation of bone fragments or bone reconstruction.

The design features and function of the CHARLOTTE™ Snap-Off Screw are substantially equivalent to the design features previously cleared under the CHARLOTTE™ Snap-Off screw and are highlighted below:

- Manufactured from ASTM F136 (Ti-6AI-4V ELI)
- Self-drilling and self-tapping features on distal threads
- Groove in head of screw around neck connection to drive mechanism to allow for snap off of drive mechanism shaft below screw head surface

The subject screws in this Special 510(k) include a change in the tip geometry of the snap-off 2.0mm diameter screw as well as the introduction of additional screw lengths to the 2.0mm and 2.7mm diameter screws to fill in sizes not previously included. Additionally, screws that are provided sterile have been added.

5. Intended Use

The CHARLOTTE™ Snap-Off Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of Small Bone Fragments
- Weil osteotomy
- Mono-cortical fixation
- Osteotomies and fractures fixation in the foot and hand

6. Technological Characteristics Comparison

The CHARLOTTE™ Snap-Off Screw and the legally marketed predicate CHARLOTTE™ Snap-Off Screw have identical indications, utilize the same instrumentation, and are identical in material. Sterilization methods have been updated to reflect the addition of products that are provided sterile.

7. Substantial Equivalence – Non-Clinical Evidence

Mechanical testing per ASTM F543-02 includes ultimate torque, insertion torque, fully-seated torque, neck break-off torque, removal torque, and axial pull-out. These test demonstrated that the performance of the subject screw is statistically equivalent or greater than the predicate screw.

8. Substantial Equivalence – Clinical Evidence

N/A

9. Substantial Equivalence – Conclusions

The design characteristics of the subject devices do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 7, 2014

Wright Medical Technologies, Inc.
Ms. Leslie Fitch
Senior Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K133713
Trade/Device Name: CHARLOTTE™ Snap-Off Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 29, 2014
Received: February 10, 2014

Dear Ms. Fitch:

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 contact 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. 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,

Vincent D. Devlin -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133713

Device Name
CHARLOTTE™ Snap-Off Screw

Indications for Use *(Describe)*

The CHARLOTTE™ Snap-Off Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of Small Bone Fragments
- Weil osteotomy
- Mono-cortical fixation
- Osteotomies and fractures fixation in the foot and hand

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth L. Frank -S

Division of Orthopedic Devices