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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 Compression Staple and Simple Staple.

Submitted By:	Wright Medical Technology, Inc.
Date:	November 4, 2004
Contact Person:	Katie Logerot
	Regulatory Affairs Specialist II
Proprietary Name:	Compression Staple and Simple Staple
Common Name:	Fixation Staple
Classification Name and Reference:	21 CFR 888.3030 Staple, Fixation, Bone – Class II
Device Product Code and Panel Code:	21 CFR 888.3030 Staple, Fixation, Bone – Class II

DEVICE INFORMATION

A. INTENDED USE

The Compression Staple and Simple Staple are indicated for fixation of bone fractures or bone reconstruction.

B. DEVICE DESCRIPTION

The design features of the Compression Staple are summarized below:

- Manufactured from stainless steel
- 10 sizes
- Barbs to prevent back out
- Diamond shape slot compression feature

The design features of the Simple Staple are summarized below:

- Manufactured from stainless steel
- Barbs to prevent back out

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the Compression Staple and Simple Staple are substantially equivalent to previously cleared fixation staples. The safety and

effectiveness of the Compression Staple and Simple Staple 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 1 8 2005

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

Re: K043059
Trade/Device Name: Compression staple and simple staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: November 4, 2004
Received: November 5, 2004

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 (240) 276-0120. 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 may be obtained 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/industry/support/index.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
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): K043059

Device Name: Compression Staple and Simple Staple

Indications For Use:

The Compression Staple is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

The Simple Staple is intended to be used for wedge osteotomy of the first phalanx (Akin osteotomy), in the treatment of hallux-valgus in order to correct a remaining valgus or pronation of the first ray, and external rotation, and wind-swept toes.

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (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 Sign-Off)
Division of General, Restorative, and Neurological Devices

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