

K092834

**510(k) Summary of Safety and Effectiveness:
HOFFMANN XPRESS LINE EXTENSION**

Submission Information

Name and Address of the Sponsor
of the 510(k) Submission:

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

OCT - 8 2009

For Information contact:

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Date Summary Prepared:

September 14, 2009

Device Identification

Proprietary Name:

Hoffmann Xpress Line Extension

Common Name:

External fixation frame components

Classification Name and Reference:

Single/multiple component metallic bone fixation
appliances and accessories, 21 CFR §888.3030

Device Product Code:

KTT

Description:

This Special 510(k) submission is intended to address the addition of 500mm (length)/15mm (diameter) connecting tubes to the predicate Hoffmann Light System, now known as Hoffmann Xpress System.

Intended Use:

The Hoffmann Xpress Line Extension does not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject tubes are provided below.

Indications for Use:

The Hoffmann® Xpress Line Extension is intended for complete and temporary fracture fixation for long bones and pelvis fractures. Specific indications include:

- Bone fracture fixation;
- Osteotomy;
- Arthodesis;
- Correction of deformity;

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- Revision procedures where other treatments or devices have been unsuccessful;
- Bone reconstruction procedures.

Statement of Technological Comparison:

The subject and predicate devices are made from an aluminum alloy (AlMgSi) and Linear Low Density Polyethylene (LLDPE). Functional and mechanical testing demonstrates the comparable mechanical and functional properties of the subject Hoffmann Xpress Line Extension to the predicate device Hoffmann Xpress (Light) System K073076.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Howmedica Osteonics Corp.
% Ms. Melissa A. Matarese
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

OCT - 8 2009

Re: K092834

Trade/Device Name: Hoffmann Xpress System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: KTT

Dated: September 14, 2009

Received: September 15, 2009

Dear Ms. Matarese:

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.

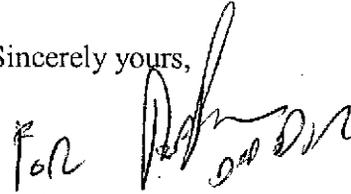
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (240) 276-3150 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

510(k) Number (if known): K092834

Device Name: Hofmann Xpress Line Extension

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- Osteotomy;
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X AND/OR Over-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

[Signature] for *MXM*
 (Division Sign-Off)
 Division of Surgical, Orthopedic,
 and Restorative Devices

510(k) Number K092834