K102601

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510(k) Summary
for the OrthoFlex Rod

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the OrthoFlex Rod

JAN 14 2011

Date Prepared: January 4, 2011

1. **Submitter:**
OrthoPro LLC
3450 Highland Drive, Ste 303
Salt Lake City, UT 84106

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** OrthoFlex Rod
Common Name: silicone toe prostheses
Classification Name: prosthesis, toe, constrained, polymer
21CFR 888.3720
KWH
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
   - Metatarsophalangeal and Interphalangeal - K022886/ K022887 (OsteoMed)
   - Shaw-Ship Rod - K905795 (Sgarlato Laboratories)
   - Swanson Hammertoe Implant - K801094 (Wright Medical Technology)

4. **Description of the device:**
The OrthoFlex Rod design is a double-stemmed flexible implant designed for the proximal interphalangeal joint of the lateral toes. It is made of silicone elastomer, and is constructed in a rod-shaped design with a thicker mid-section spacer or collar.

5. **Substantial equivalence claimed to predicate devices**
OrthoFlex Rod is substantially equivalent to the OsteoMed, Sgarlato Laboratories and Wright Medical Technology devices in terms of intended use, design, and materials used.

6. **Intended Use:**
The indications for the OrthoFlex Rod include:
   - Semi-rigid or rigid hammertoe deformity associated with degenerative arthritis
   - Semi-rigid or rigid hammertoe deformity associated with rheumatoid arthritis
   - Revision of a failed arthroplasty or arthrodesis

7. **Clinical Test Summary**
No clinical studies were performed

8. **Conclusions Nonclinical and Clinical**
OrthoFlex Rod is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

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

OrthoPro LLC
% The OrthoMedix Group, Inc.
Mr. J. D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

JAN 14 2011

Re: K102601
Trade/Device Name: OrthoFlex Rod
Regulation Number: 21 CFR 888.3720
Regulation Name: Toe joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KWH
Dated: January 05, 2011
Received: January 11, 2011

Dear Mr. Webb:

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

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Indications for Use

510(k) Number (if known): _____

Device Name: OrthoFlex Rod

Indications for Use:

The indications for the OrthoFlex Rod include:

- Semi-rigid or rigid hammertoe deformity associated with degenerative arthritis
- Semi-rigid or rigid hammertoe deformity associated with rheumatoid arthritis
- Revision of a failed arthroplasty or arthrodesis

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

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

510(k) Number K102609