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OSTEOMED CORPORATION

510(k) Summary

Device Proprietary Name:	OsteoMed Interphalangeal Flexible Stabilizing Rod System
Device Common Name:	Toe Implants, Silicone
Classification Name:	Prosthesis, Toe Joint, Constrained, Polymer
Name of Submitter:	OsteoMed Corporation 3750 Realty Road Addison, Texas 75001 Phone: (972) 241-3401 Fax: (972) 241-3449
Contact Person:	Dawn T. Holdeman
Date Prepared:	August 23, 2002

Summary:

This submission describes the OsteoMed Interphalangeal Flexible Stabilizing Rod System intended for indications commonly found in the interphalangeal joints; semi-rigid or rigid hammertoe deformity; angular deformity; impaired function and stability; pain; impaired toe length ratio. OsteoMed Interphalangeal Flexible Stabilizing Rod Implants are intended for single use only.

The OsteoMed Interphalangeal Flexible Stabilizing Rod System is a stemmed flexible implant specifically designed for replacement of the interphalangeal joints of the lesser toes. It is constructed of medical grade silicone elastomer. The OsteoMed Interphalangeal Flexible Stabilizing Rods are offered in diameters of 2.0mm through 2.5mm. Drills and sizers will also be a part of the system.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Sgarlato Laboratories Shaw-Ship Rod, Hammer Toe Implant.

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed Interphalangeal Flexible Stabilizing Rod System does not raise any new safety or effectiveness issues.

3750 Realty Road
Addison, Texas 75001-4311
(972) 241-3401 FAX: (972) 241-3507
Customer Service: (800) 456-7779

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2002

Ms. Dawn T. Holdeman
Regulatory Affairs / Document Control
OsteoMed Corporation
3750 Realty Road
Addison, Texas 75001-4311

Re: K022887
Trade/Device Name: Interphalangeal Flexible Stabilizing Rod System
Regulation Numbers: 21 CFR 888.3720
Regulation Names: Toe joint polymer constrained prosthesis
Regulatory Class: II
Product Code: KWH
Dated: August 29, 2002
Received: August 30, 2002

Dear Ms. Holdeman:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/dsma/dsmamain.html

Sincerely yours,

for 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

OsteoMed "Indications for Use" Submission

510(k) Number: K022887

Device Name:	OsteoMed Interphalangeal Flexible Stabilizing Rod System
Indication for Use:	Indications commonly found in the interphalangeal joints; semi-rigid or rigid hammertoe deformity; angular deformity; impaired function and stability; pain; impaired toe length ratio. Implants are single use only.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 810.109)

Over-The Counter-Use _____
(Optical Format 1-)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K022887