

510 (k) Summary

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Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

JAN 17 2003

Prepared: October 18, 2002
Applicant: Futura Biomedical
990 Park Center Drive, Suite H
Vista, CA 92083
Telephone: 760-599-1670
Fax: 760-599-1675
Contact: Louise M. Focht

Device Name: Prosthesis, Toe, Constrained, Polymer
Device Trade Name: Lesser Metatarsal Phalangeal Joint Implant
Device Classification: Class II
Reviewing Panel: Orthopedic
Regulation Number: 888.3720
Product Code: 87 KWH
Original Predicate Device: Sutter Lesser Metatarsal Phalangeal Joint
Prosthesis K 820813, Currently sold by
Futura Biomedical
Registration Number: 2030833
Owner Operator Number: 9028319

Device Description:

The Lesser Metatarsal Phalangeal Joint Implant is a double-stemmed silicone prosthesis, intended to supplement lesser metatarsophalangeal joint arthroplasty. The implant is designed to act as a dynamic joint spacer between the resected head of the metatarsal and base of the proximal phalanx.

Indications for Use:

Futura Biomedical Lesser Metatarsal Phalangeal Joint Implant is indicated for:

- Partial or complete dislocation of the lesser metatarsophalangeal joint
- Pain Associated with rheumatoid or osteoarthritis

- Repair of unsuccessful arthroplasties of the lesser metatarsophalangeal joint
- Stiffness at the lesser metatarsophalangeal joint associated with joint disease
- Kohler's disease
- Hammer toe deformity where the proximal phalanx is dorsally located on the metatarsal in a fixed contracture state

Comparison to the Original Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Sutter Lesser Metatarsal Phalangeal Joint Prosthesis.

Regulatory Class: II
Product Code: 87 KWH

Table Comparison of original Sutter Biomedical Lesser Metatarsal Phalangeal Joint Prosthesis to the new configuration Lesser Metatarsal Phalangeal Joint.

| <i>Item</i> | <i>Sutter Biomedical (LMP)</i> | <i>Proposed (LMP) product configuration</i> |
|---------------------|--|--|
| Product Name | Sutter Lesser Metatarsal Phalangeal Joint Prosthesis | Lesser Metatarsal Phalangeal Joint Prosthesis |
| Use | Single use | Single use |
| Fixation | stem in intramedullary canal | stem in intramedullary canal |
| Constraint | Constrained | Constrained |
| Material | Silicone | Silicone |
| Sizes | 8 sizes, S5, S7, M5, M7, M10, L5, L7, L10 | 4 sizes 20, 30, 40, 50 |
| Indications for use | <p>Partial or complete dislocation of the lesser metatarsophalangeal joint</p> <p>Pain Associated with rheumatoid or osteo-arthritis</p> <p>Repair of unsuccessful arthroplasties of the lesser metatarsophalangeal joint</p> <p>Stiffness at the lesser metatarsophalangeal joint associated with joint disease</p> <p>Kohler's disease</p> <p>Hammer toe deformity where the proximal phalanx is dorsally located on the metatarsal in a fixed contracture state</p> | <p>Partial or complete dislocation of the lesser metatarsophalangeal joint</p> <p>Pain Associated with rheumatoid or osteo-arthritis</p> <p>Repair of unsuccessful arthroplasties of the lesser metatarsophalangeal joint</p> <p>Stiffness at the lesser metatarsophalangeal joint associated with joint disease</p> <p>Kohler's disease</p> <p>Hammer toe deformity where the proximal phalanx is dorsally located on the metatarsal in a fixed contracture state</p> |

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Similarities of the Sutter Lesser Metatarsal Phalangeal Joint Prosthesis and the Futura Biomedical Lesser Metatarsal Phalangeal Joint Prosthesis include;

Both devices are intended for single use only; Both devices are intended for surgical implantation longer than 30 days; Both devices are placed into the intramedullary canal of the lesser metatarsal and phalangeal bones; Both devices are made of the same industry standard materials. No new materials are introduced in either product; Both devices are comparably sized; Both devices have the identical for use.

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Ms. Louise M. Focht
Futura Biomedical
990 Park Center Drive, Suite H
Vista, California 92083

Re: K023531

Trade Name: Lesser Metatarsal Phalangeal Joint Implant
Regulation Number: 21 CFR 888.3720
Regulation Name: Toe joint polymer constrained prosthesis
Regulatory Class: II
Product Code: KWH
Dated: October 18, 2002
Received: October 21, 2002

Dear Ms. Focht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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.

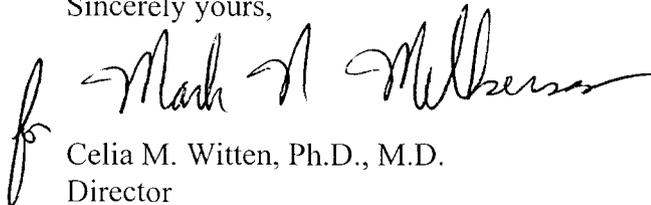
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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

510 (k) Number (If Known): K023531
Device Name: Lesser Metatarsal Phalangeal Joint Implant

Indications for Use:

Futura Biomedical Lesser Metatarsal Phalangeal Joint Implant is indicated for:

- Partial or complete dislocation of the lesser metatarsophalangeal joint
- Pain Associated with rheumatoid or osteo-arthritis
- Repair of unsuccessful arthroplasties of the lesser metatarsophalangeal joint
- Stiffness at the lesser metatarsophalangeal joint associated with joint disease
- Kohler's disease
- Hammer toe deformity where the proximal phalanx is dorsally located on the metatarsal in a fixed contracture state

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR § 801.109)

OR

Over-the-Counter-Use _____
(Optional Format 1-2-96)

for Mark H. Melkers

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K023531