JUN 30 1998

FUTURA BIOMEDICAL K981194

510(k) Summary

Submitted by:
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Date of preparation:
March 30, 1998

Trade Name:
Futura Biomedical Flexible Great Toe Implant

Common Name:
Flexible Great Toe Implant

Classification Name:
Constrained Polymer Toe Prosthesis per 888.3720 (Class II)

Substantially Equivalent to (predicate device):
Swanson Flexible Hinge Toe Implant by Dow Corning, 510(k) number K780132 (now offered by Wright Medical Technology, Inc., Arlington, TN).

Description/Intended Use:
The Flexible Great Toe implant is a double-stemmed silicone prosthesis to supplement first metatarsophalangeal joint arthroplasty. The implant is designed to act as a dynamic joint spacer between the head of the 1st metatarsal and base of the proximal phalanx. A grommet option is offered for surgeons who choose to utilize grommets in their surgical procedure. This is consistent with the description and intended use of the Swanson Flexible Hinge Toe Implant.

Indications for use of this implant are:

- Hallux limitus or hallux rigidus.
- Painful rheumatoid arthritis.
- Hallux abducto valgus associated with arthritis.
- Unstable or painful joint from previous surgery.

Technological Characteristics:
The Futura Flexible Great Toe and Predicate device are double-stemmed, silicone implants with a hinged midsection. They both offer titanium press fit grommets.

The angled hinge block of the Flexible Great Toe allows for the normal anatomic insertion of the flexor hallucis brevis tendon to be maintained and removes less of the inferior aspect of the metatarsal head to mitigate sesamoid impingement. The tapered stems and implant face are designed based on the geometry of the resected faces of the proximal phalanx and metatarsal.

There are currently no performance standards for great toe silicone joint implants. The American Society for Testing of Materials (ASTM) has developed voluntary standards for the materials used in the grommets:

F 67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1998

Mr. Jamal D. Rushdy
General Manager
Futura Biomedical, L.L.C.
9369 Carroll Park Drive, Suite A
San Diego, California 92121

Re: K981194
Trade Name: Flexible Great Toe Implant
Regulatory Class: II
Product Code: KWH
Dated: March 30, 1998
Received: April 2, 1998

Dear Mr. Rushdy:

We have reviewed your Section 510(k) 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K981194

Device Name: **Flexible Great Toe**

Indications for Use:

- Hallux limitus or hallux rigidus.
- Painful rheumatoid arthritis.
- Hallux abducto valgus associated with arthritis.
- Unstable or painful joint from previous surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981194