OCT 0 4 2002

K023086
page 1 of 2

510 (k) Summary

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

Prepared: September 13, 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:	Classic Great Toe Implant
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3720
Product Code:	87 KWH
Original Predicate Device:	Futura Biomedical Flexible Great Toe Implant – k981194
Registration Number:	2030833
Owner Operator Number:	9028319

Device Description:

The Classic Great Toe Implant is a double–stemmed silicone prosthesis, intended to supplement first metatarsophalangeal joint srthroplasty. The implant is designed to act as a dynamic joint spacer between the resected head of the first metatarsal and base of the proximal phalanx.

Indications for Use:

Futura Biomedical Classic Great Toe Implant is indicated for:

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

Comparison to the Original Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Futura Biomedical Flexible Great Toe Implant

Regulatory Class: II
Product Code: 87 KWH

Comparison of original Futura Biomedical Flexible Great Toe Implant to the new configuration the Classic Great Toe Implant.

Item	*Original Futura Product*	*Proposed product configuration*
Product Name	Flexible Great Toe Implant	Classic Great Toe Implant
Use	Single use	Single use
Fixation	Stem in intramedulary canal	stem in intramedulary canal
Constraint	constrained	constrained
Material	Silicone	Silicone
Sizes	4 sizes, 20, 30, 40, 50	4 sizes 20, 30, 40, 50
Indications for use	Hallux limitus or hallux rigidus	Hallux limitus or hallux rigidus
	Painful rheumatoid arthritis	Painful rheumatoid arthritis
	Hallux abducto valgus associated with arthritis	Hallux abducto valgus associated with arthritis
	Unstable or painful joint from previous surgery	Unstable or painful joint from previous surgery

Similarities of the Futura Flexible Great Toe Implant and Classic Great Toe Implant 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 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 4 2002

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

Re: K023086
Trade Name: Classic Great Toe Implant
Regulation Number: 21 CFR 888.3720
Regulation Name: Toe joint polymer constrained prosthesis
Regulatory Class: II
Product Code: KWH
Dated: September 13, 2002
Received: September 17, 2002

Dear Mr. 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.

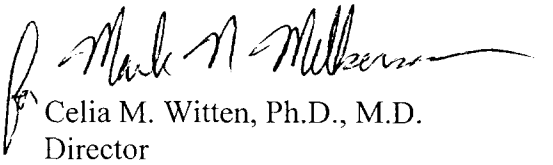
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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 and additionally 21 CFR Part 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" (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,



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): K023086
Device Name: Classic Great Toe Implant

Indications for Use:

Futura Biomedical Classic Great Toe Implant is indicated for:

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

Prescription Use Yes/No or Over the counter use Yes/No

for Mark N Milhous

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

510(k) Number K023086