FUTURA BIOMEDICAL

JUN 20 1997

K971047

## 510(k) Summary

Submitted by:
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Date of preparation:
June 11, 1997

Trade Name:
Futura Biomedical Metal Hemi Toe Implant

Common Name:
Metal Hemi Toe Implant

Classification Name:
Phalangeal Hemi-Toe Prosthesis per 888.3730 (Class II)

Substantially Equivalent to (predicate device):
Swanson Titanium Great Toe Implant by Dow Corning, 510(k) number K864492

Description/Intended Use:
The Metal Hemi Toe implant is a cobalt chrome alloy, one piece implant to supplement first metatarsal phalangeal joint arthroplasty. The implant is designed to replace the base of the proximal phalanx and provide a smooth articular surface for the adjacent metatarsal head. Primary fixation of the grit-blasted version of the device is via a press fit. This is consistent with the description and intended use of the Swanson Titanium Great Toe Implant. The titanium plasma spray coated version of this device is intended for use with bone cement.

Indications for use of this implant are:

- Hallux limitus or hallux rigidous.
- Painful hallux valgus.
- Revision of failed previous surgery.
- Painful arthritis.

Technological Characteristics:
The implant has an anatomic design which helps minimize the complications often seen with arthroplasty of this joint such as: joint instability, shortening of the hallux, painful or limited range of motion. The thin inferior aspect allows the normal anatomic insertion of the flexor brevis tendon to be maintained.

There are two versions of the Metal Hemi Toe. One version has a roughened grit blasted surface on the stem and back surfaces in contact with the resected base of the phalanx. The other version is coated with a rough coating of titanium plasma spray to encourage osseous ingrowth.

The main difference between the Metal Hemi Toe and the Swanson Titanium Great Toe is the material. While the Metal Hemi Toe and Swanson Titanium Great Toe are both metallic implants, the Metal Hemi Toe is fabricated mainly of a Cobalt Chrome Alloy rather than Titanium. Both materials are widely used in metallic implants, but Cobalt Chrome is generally favored as an articular surface. Cobalt Chrome is currently used as

an articular surface for a phalangeal hemi toe (ref 510(k) K911378 BIOPRO, INC.), and has a 40 year history, as reported by Townley and Taranow.
The American Society for Testing of Materials (ASTM) has developed voluntary standards for the materials used in the Metal Hemi Toe:

F 67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications
F 75, Standard Specification for Unalloyed Cast Cobalt-Chromium-Molybdenum for Surgical Implant Applications

Conclusions:

The Metal Hemi Toe and Swanson Titanium Great Toe are both metallic hemi prosthesis used to supplement first metatarsal phalangeal joint arthroplasty. They are both one-piece, single stemmed implants which press fit into the intramedullary canal of the proximal phalanx. They both have a curved articular surface for the first metatarsal head to articulate against. The Metal Hemi Toe is offered in sizes that fit within the size range of the Swanson Titanium Great Toe Implant.

The main difference between the two devices is the materials. Cobalt chrome is commonly used in implant fabrication. There are published studies of metallic hemi toe implants using either cobalt chrome (Townley and Taranow) or titanium (Leavitt et. al.), and numerous studies of the use of both of these materials in general in orthopaedic implants. In addition, there are published ASTM standards for the component materials which are intended for surgical implant applications. Based on these data, and the comparisons described above, we feel the material difference of the substrate material (cobalt chrome) from the predicate device (titanium) does not adversely affect the safety and effectiveness of the device, and that the Futura Biomedical Hemi Toe Implant is substantially equivalent to the Dow Corning Swanson Titanium Great Toe Implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

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

Re: K971047
Trade Name: Metal Hemi Toe Implant
Regulatory Class: II
Product Code: KWD
Dated: March 19, 1997
Received: March 21, 1997

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,

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

510(k) Number: **K971047**

Device Name: **Metal Hemi Toe**

**The titanium plasma spray coated version of this device is intended for use with bone cement.**

Indications for Use:

- **Hallux limitus or hallux rigidous.**
- **Painful hallux valgus.**
- **Revision of failed previous surgery.**
- **Painful arthritis.**

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971047

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use_____