DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 14, 2016

Ms. Louise M. Focht
Futura Biomedical
990 Park Center Drive, Suite H
Vista, California 92081

Re: K033046
Trade/Device Name: Subtalar Peg Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MJW
Dated: September 29, 2003
Received: September 29, 2003

Dear Ms. Focht:

This letter corrects our substantially equivalent letter of December 23, 2003.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) Number (If Known): K033046
Device Name: Subtalar Peg Implant

Indications for Use:

The Futura Biomedical Subtalar Peg Implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. Examples include:

Flat foot treatment in children and adolescents
Congenital flat foot
Unsuccessful long term orthopaedic treatment (shoes, insoles...)
Tarsal coalitions
Painful flat foot
Supple deformity in posterior tibial tendon dysfunction
Paralytic flat foot
Subtalar instability

This device is intended to be fixed with bone cement.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Device Evaluation

K033046

DEC 2 3 2003

K033046

510 (k) Summary

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

Prepared: December 22, 2003

Applicant: Futura Biomedical
990 Park Center Drive
Vista, CA 92081

Telephone: 760-599-1670
Fax: 760-599-1675
Contact: Louise M. Focht

Device Name:	Subtalar Peg Implant
Device Trade Name:	Subtalar Peg Implant
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	
Product Code:	87 MJW
Predicate Device:	K792670– Smith Subtalar Peg
Registration Number:	2030833
Owner Operator Number:	9028319

Device Description:

The Futura Biomedical Implant is a one-piece device made of UHMWPE or Cobalt Chromium with titanium plasma spray on the stem, intended to be implanted into the calcaneus of the foot. The implant is designed in 13 sizes and two configurations. The implant which is used in the treatment of excessive motion of the talus relative to the calcaneus acts as a spacer for the joint, maintaining the joint space, allowing for range of motion, but limiting excessive pronation.

Indications for Use:

The Futura Biomedical Subtalar Peg Implant is intended to treat hyperpronated foot and stabalize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. Examples include:

Flat foot treatment in children and adolescents
Congenital flat foot
Unsuccessful long term orthopaedic treatment (shoes, insoles...)
Tarsal coalitions

Painful flat foot
Supple deformity in posterior tibial tendon dysfunction
Paralytic flat foot
Subtalar instability

This device is intended to be fixed with bone cement.

Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Wright Medical STA-Peg implant.

Regulatory Class: II
Product Code: 87 MJW

Table 1. Comparison of Futura Biomedical and Wright Medical STA-Peg Implant

Item	*Futura Product*	*Wright Medical Product*
Product Name	Subtalar Peg Implant	STA-Peg Implant
Use	Single use	Single use
Fixation	Stem in bone	Stem in bone
Constraint	Non constrained	non constrained
Material	UHMWPE or CoCr/CpTi	UHMWPE
Sizes	5 sizes, two configurations (13 sizes)	5 sizes
Indications for use	The Futura Biomedical Subtalar Peg Implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. Examples include: Flat foot treatment in children and adolescents Congenital flat foot Unsuccessful long term orthopaedic treatment (shoes, insoles...) Tarsal coalitions Painful flat foot Supple deformity in posterior tibial tendon dysfunction Paralytic flat foot Subtalar instability This device is intended to be fixed with bone cement.	The STA-Peg implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. Examples include: Flat foot treatment in children and adolescents Congenital flat foot Unsuccessful long term orthopaedic treatment (shoes, insoles...) Tarsal coalitions Painful flat foot Supple deformity in posterior tibial tendon dysfunction Paralytic flat foot Subtalar instability

Similarities of the Futura Biomedical Subtalar Arthrorisis Implant and the Wright Medical STA-Peg Implant include:

Both devices are: intended for single use only; intended for surgical implantation longer than 30 days; both devices are placed into the calcaneus of the foot, allowing normal subtalar joint motion while blocking excessive pronaton and resulting sequela; both devices are made of industry standard materials, no new materials are introduced in either product; Both devices are comparably sized; both devices have the same indications 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.