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510K SUMMARY OF SAFETY AND EFFECTIVENESS

The Signal Medical Corporation Great Toe Implants are manufactured from ASTM F75 Cobalt Chrome. The porus coating is ASTM F75 sintered beads, -45+60 mesh. The device is intended for non-cemented use. The stem of the device is intended to be inserted into the proximal end or base of the first phalangel bone. The convex surface of the implant is intended to articulate with the distal end or head of the first metatarsal bone. The design is made available in multiple sizes equivalent to the toe implants in the Townley Great Toe Joint 510K (K911378) and the Zimmer Great Toe 510K (K823405).

Indications for use

1. Osteoarthritis
2. Where the use of a more conservative procedure has failed or is unacceptable.

Contact Information

If further information is required please contact Dr. Louis Serafin, Signal Medical Corporation, 3777 Lapper Road Suite 3C, Port Huron, Michigan 48060, phone (810) 966-3917.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Louis A. Serafin, Jr., M.D.
Signal Medical Corporation
3777 Lapeer Road, Suite 3C
Port Huron, Michigan 48060

Re: K021063
Trade/Device Name: Great Toe Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: March 19, 2002
Received: April 2, 2002

Dear Dr. Serafin, Jr.:

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.

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): K021063

Device Name: ~~Great Toe Implant~~

Indications For Use:

Osteoarthritis

Where the use of a more conservative procedure has failed or is unacceptable.

The device is intended for non-cemented use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use___

510(k) Number K021063

(Optional Format 1-2-96)