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

April 17, 2015

Osteotec Limited
Ms. Elizabeth Clinton-Parker
Quality & Regulatory Officer
9 Silver Business Park, Airfield Way
Christchurch, Dorset
BH23 3TA
United Kingdom

Re: K140453
Trade/Device Name: OSTEOTEC Silicone Finger Implant
Regulation Number: 21 CFR 888.3230
Regulation Name: Finger joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KYJ
Dated: March 12, 2015
Received: March 16, 2015

Dear Ms. Clinton-Parker:

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 Part 801); 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 Part 801), 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,

Lori A. Wiggins -S

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

Enclosure

Section 4
OSTEOTEC Silicone Finger Implant
510(k)

Indications for Use

510(k) number (if known):
K140453

Device name:
OSTEOTEC Silicone Finger Implant

Indications for use:
The OSTEOTEC Silicone Finger Implant is a single piece flexible joint replacement implant for the metacarpophalangeal (MCP) joint and proximal interphalangeal (PIP) joints in the hand; commonly due to rheumatoid arthritis or osteoarthritis.

Prescription Use __Yes_____ AND/OR Over-The-Counter Use ___No__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5
OSTEOTEC Silicone Finger Implant
510(k)

510(k) Summary
(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

1. Submitter's name and address:

Osteotec Limited
9 Silver Business Park
Airfield Way
Christchurch
Dorset
BH23 3TA
U.K.

FDA Establishment Registration No. 3008395366

2. Submitter's telephone number and fax number:

Tel: 011 44 1202 487885
Fax: 011 44 1202 487886

3. Contact person:

Elizabeth Clinton-Parker – Auditor, QA/RA Officer

4. Date this 510(k) summary prepared:

March 28, 2015

5. Trade/proprietary name of the device:

OSTEOTEC Silicone Finger Implant

6. Common Name:

Finger joint Polymer Constrained Prosthesis

7. Classification name and number of the device*:*

FDA Classification Name – Finger joint polymer constrained prosthesis
FDA Regulation Number - 21CFR 888.3230
FDA Product Code - KYJ

8. Legally marketed predicate devices to which substantial equivalence is claimed:

Swanson Flexible Finger Joint Implant device is a "pre-amendment device" and is currently legally marketed in the U.S. by:

Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN USA 38002

510(k) No. – Pre-amendment device
FDA Decision Date – N/A
FDA Device Class - 2
FDA Classification Name – Finger joint polymer constrained prosthesis
FDA Regulation Number - 21CFR 888.3230
FDA Product Code - KWF

Section 5
OSTEOTEC Silicone Finger Implant
510(k)

Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis has been legally marketed in the U.S. since 2002 by:

Small Bone Innovations, Inc.
1380 South Pennsylvania Ave.
Morrisville, PA 19067

510(k) No. K013629
FDA Decision Date – 25 January 2002
FDA Device Class - 2
FDA Classification Name – Finger joint polymer constrained prosthesis
FDA Regulation Number - 21CFR 888.3230
FDA Product Code - KYJ

9. Description of the device that is the subject of this premarket notification:

The OSTEOTEC Silicone Finger Implant is a single piece flexible joint replacement implant for the metacarpophalangeal (MCP) joint and proximal interphalangeal (PIP) joints in the hand; commonly due to rheumatoid arthritis or osteoarthritis.

The one-piece device consists of a specifically designed, central, flexible hinge attached to an elongated rectangular-based pyramid stem on either side. The stems insert into the intramedullary canals of the metacarpals and/or phalanges and have a slight surface texture.

The OSTEOTEC Silicone Finger Implant is manufactured from implant grade silicone. It is available in eleven, evenly scaled sizes to meet various anatomical requirements.

The OSTEOTEC Silicone Finger Implant is not designed for use with any other devices. The implant has dedicated instrumentation which is required to prepare the bone for the implant and sizers to ensure that the correct size of product is used.

10. Intended use and indication for use:

The OSTEOTEC Silicone Finger Implant is a single piece flexible joint replacement implant for the metacarpophalangeal (MCP) joint and proximal interphalangeal (PIP) joints in the hand; commonly due to rheumatoid arthritis or osteoarthritus.

11. Technological characteristics:

The OSTEOTEC Silicone Finger Implant is manufactured from silicone implant grade Nusil MED-4757 material. The product consists of a range of 11 flexible silicone implants (sizes 00-9) intended for joint replacements of the MCP and PIP joints of the hand.

12. Substantial Equivalence Determination

The direct patient contacting material of the OSTEOTEC Silicone Finger Implant is the silicone supplied by Nusil as product code MED-4757.

Section 5
OSTEOTEC Silicone Finger Implant
510(k)

Clastogenicity has been assessed in a mammalian system to provide data to further support the biocompatibility of the device.

Assessments of the dynamic mechanical properties, of the subject and predicate devices, via side by side flexion testing to 10 million cycles, (Size 6 and Size 00) were conducted.

Assessments of the static mechanical properties, of the subject and predicate devices, via side by side static testing of the bulk materials, (Nusil MED 4757 and Nusil MED 4755), were conducted.

Drop testing has been performed to ensure that the packaging developed for the OSTEOTEC Silicone Finger is suitable and can maintain its sterile barrier throughout storage and distribution.

A shelf life of 5 years has been established for the OSTEOTEC Silicone Finger Implant based on functional testing after sealed and irradiated packages were stored in a recommended condition for a period greater than 6 years.

The instrument tray has been validated to perform effectively during cleaning, steam sterilization and drying time.

Based on the results from the above test data it is concluded that the OSTEOTEC Silicone Finger Implant is substantially equivalent to the above named predicate devices.