510(k) SUMMARY

As required by section 807.92

1. GENERAL INFORMATION

Type of 510(k)	TRADITIONAL
Trade Name	NEOTIS Plate and Screws
CFR section	21CFR 888.3030
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Device panel	ORTHOPEDIC
Product Code	HRS: PLATE, FIXATION, BONE HWC : SCREW, FIXATION, BONE
Class	II
Legally marketed predicate devices	K100604 and K120818 OTIS-C Plus® Plate Fixation System manufactured by SBM Sciences for Bio Materials.
Submitter	SCIENCE FOR BIOMATERIALS Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES – FRANCE Registration Number : 3004549189
Contact	Denis CLEMENT, CEO Tel : +33 (0)5 62 42 21 01 Fax : +33 (0)5 62 42 21 00 e-mail : denis.clement@sbm-fr.com Regulatory contact : Anne COSPIN-LATAPIE anne.cospin@sbm-fr.com

2. DEVICE DESCRIPTION

The NEOTIS plate is designed for medial approach High Tibial Osteotomy stabilization. Anatomically shaped, thin and short, the NEOTIS plate enables minimally invasive surgery. The changes brought by the NEOTIS plate are as follows (vs. OTIS-C Plus plate):

- The proximal temporary screw is replaced with a pin that offers a simpler and faster placement of the plate. The area of the cortical bone drilled through the process is also reduced.
- The distal temporary screw is replaced with an AO screw in order to maintain compression. The compression will be maintained by the 4 permanent 6.5 mm screws (OTIS screws).

3. INDICATIONS FOR USE

NEOTIS plate is intended to be used in conjunction with OTIS screws to provide fixation following Proximal Tibial opening wedge osteotomies.

4. PERFORMANCE DATA

The mechanical properties are the same as for the previous OTIS-C Plus, the only changes occur during the placement of the plate. No clinical data has been presented. Non-clinical performance testing includes a cadaver study that confirms the level of compression induced during the placement of the plate.

5. SUBSTANTIAL EQUIVALENCE

The NEOTIS plate is substantially equivalent to its predicate device OTIS-C Plus plate (K100604 and K120818). Verification and validation tests demonstrate that modified the NEOTIS plate is as safe, as effective, and performs as safely and effectively as its predicate device.

Summary preparation date: June 2, 2014

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

June 3, 2014

Science for Biomaterials (Sciences et Bio Matériaux)
Mr. Denis Clement
General Manager
ZI du Monge
F 65100 Lourdes - FRANCE

Re: K140226
Trade/Device Name: NEOTIS Plate and Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: April 11, 2014
Received: April 14, 2014

Dear Mr. Clement:

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" (21 CFR 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,

Ronald P. Jean -S for

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K140226
Device Name: NEOTIS Plate and Screws
Indications for Use:

NEOTIS Plate is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial Opening wedge osteotomies.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth [illegible] Frank -S

Division of Orthopedic Devices