K133061
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510(k) SUMMARY

NLT SPINE's eSPIN System

As required by 21 C.F.R. § 807.92

Sponsor:

NLT SPINE Ltd.
6 Yad Harutzim St.
Kfar-Saba
Israel 4464103

NOV 27 2013

Contact Person:
Eti Zinger
Regulatory Affairs Director
NLT SPINE Ltd.
Tel: +972-3-6344514
Fax: +972-3-6341599
Eti.z@nlt-spine.com

Date Prepared: September 27, 2013

Name of Device: eSPIN System

Common or Usual Name: Arthroscope and Accessories

Classification Name: Arthroscope and Accessories
21 CFR §880.1100
Product Code HRX

Predicate Devices

- NLT SPINE eSPIN K120553, K130057
- Medtronic Inc. Midas Rex K081475

Intended Use / Indications for Use

The eSPIN System is intended for use in cutting and grinding intervertebral disc material during discectomy for fusion procedures in L2-S1 spinal segments in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e. posterior pedicle screw and rod systems).

Technological Characteristics

The eSPIN System consists of access and positioning instruments to access the disc space and to position the hand-piece for discectomy, a handpiece, disposable cutting tips, a suction tube & alignments guide and electrical motor unit.

Performance Data

Performance testing in bench (e.g. system mechanism durability & functionality) demonstrated that the eSPIN System is substantially equivalent to its predicate.

Substantial Equivalence

The eSPIN System is as safe and effective as its predicate devices. The eSPIN System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the eSPIN System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the eSPIN System is as safe and effective as its predicate devices. Thus, the eSPIN System is substantially equivalent.

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

NLT SPINE LTD
% John J. Smith, M.D., J.D.
Hogan Lovells US LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

November 27, 2013

Re: K133061
Trade/Device Name: eSPIN System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: September 27, 2013
Received: September 27, 2013

Dear Dr. Smith:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K133061

Device Name: eSPIN System

Indications for Use:

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Prescription Use ___X___ (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)

DSD—Division Sign-Off

Division of Surgical Devices

510(k) Number: K133061

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=130036 9058
Date: 2013.11.25 07:52:30 -05'00'

for BSA

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