



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2016

NCS Lab Srl
% Christine Brauer, Ph.D.
Regulatory Affairs Consultant
Brauer Device Consultants, LLC
7 Trail House Court
Rockville, Maryland 20850

Re: K160500

Trade/Device Name: Elite SPK, Compasso, Elite SPK Kit
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 22, 2016
Received: February 23, 2016

Dear Dr. Brauer:

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); 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K160500

Device Name

Elite SPK, Elite SPK Kit and Compasso

Indications for Use (Describe)

The implantable device Elite SPK is intended for the attachment of soft tissue to bone during arthroscopic or open treatment of rotator cuff tears. It is intended to be implanted using the Compasso surgical instruments.

Compasso is a series of surgical instruments intended for use for the implantation of the Elite SPK or the Sharc-FT bone anchor.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k) Application

NCS Lab Srl
Via Pola Esterna 4/12
Carpi (MO), Italy 41012

1.2 Official Correspondent

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Regulatory Affairs Consultant
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7 Trail House Court
Rockville, MD 20850

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E-mail: chris.brauer@comcast.net

1.3 Devices Subject of this 510(k)

Elite SPK
Compasso
Elite SPK Kit

1.4 Date of Preparation

April 18, 2016

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

2.1 Trade/Proprietary Name

This 510(k) application is for the following devices:

- Elite SPK, a sterile, single-use implantable suture anchor;
- Compasso, a series of reusable surgical instruments used to implant the Elite SPK; and,
- Elite SPK Kit, a sterile, single-use implantable suture anchor and sutures.

2.2 Common/Usual Name

Bone Anchor
Orthopedic Manual Surgical Instruments to Implant the Bone Anchor

2.3 Classification Information

Classification Name:	Smooth or Threaded Metallic Bone Fixation Fastener
Classification Regulation:	888.3040
Regulatory Class:	II
Product Code:	MBI – Fastener, Fixation, Nondegradable, Soft Tissue
Panel:	Orthopedic

3 PREDICATE DEVICE

The predicate device is as follows:

- NCS Lab Srl's NCS Share FT System, which was cleared through 510(k) application K120356.¹

The following reference device was considered in analysis of the technological characteristics of the device materials and certain design aspects.

- Reference device for discussion of device materials and partially threaded design: Quattro Link Knotless Anchors, manufactured by Cayenne Medical, and cleared via K122314

The Elite SPK may be provided in a kit form with sutures. The sutures have previously received clearance from FDA (Riverpoint Medical Force Fiber, K100006), and are provided in their final, sterilized form to NCS Lab Srl.

4 DEVICE DESCRIPTION

The Elite SPK is an implantable bone anchor device designed to ensure the fixation of soft tissues (especially tendons) to bone, during the repair of injuries to the shoulder performed with open or arthroscopic technique. The implantable anchor is made of polyether ether ketone (PEEK), and allows the surgeon to attach the injured tendon to the humerus using a transosseous "double row" technique. The ELITE SPK anchor is suitable for a 3 mm in diameter hole, and is provided sterile for single use.

The Compasso is a series of manual surgical instruments to implant the Elite SPK. Instruments in contact with human body are made of Stainless Steel in conformity with ISO 5832-1, while other components not in contact with the patient are made of stainless steel, aluminum and laser sintering polyamide.

¹ The tradename of the device was changed from the NCS Fish-Fit MD System to the NCS Share FT System after clearance.

The Elite SPK may be provided in a kit form with sutures for physician convenience. The sutures are provided in their final, sterile form in the original packaging from the manufacturer. FDA has previously cleared the provided sutures in 510(k) application K100006; specifically, the kit includes the HS Fiber Sutures.

5 INDICATION FOR USE

The indication for use statement is provided below.

The implantable device Elite SPK is intended for the attachment of soft tissue to bone during arthroscopic or open treatment of rotator cuff tears. It is intended to be implanted using the Compasso surgical instruments.

Compasso is a series of surgical instruments intended for use for the implantation of the Elite SPK or the Sharc-FT bone anchor.

6 COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The Elite SPK and the predicate device share the same intended use. Both devices are intended for use during arthroscopic or open surgeries to repair rotator cuff injuries. Both devices serve the same primary function: namely, to secure the tendons to the bone during healing. Both devices are used by the same health care professionals (orthopedic surgeons) in the same target patient population: adults who require surgical repair of rotator cuff injuries. Both devices are implanted into a cavity drilled into the bone, are implanted using the same surgical instruments and remain implanted in the bone.

7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Elite SPK and the predicate share certain technological features, but also have some differences. The primary difference between the Elite SPK and the Sharc FT are in materials and design. The Elite SPK is made from polyether ether ketone (PEEK) whereas the Sharc FT is made of titanium. The Elite SPK incorporates a screw type design with a wider contact head and partially threaded (referred to as side flaps or wings), whereas the Sharc FT consists of a deformable U-shape body design. Both devices have heads with eyelets to pass sutures.

Other bone anchors are made from PEEK and are available in a variety of designs included “threaded” (either full or partially) or “smooth” screw-shape designs. One such bone anchor, the Quattro Link Knotless Anchors, manufactured by Cayenne Medical, and cleared via K122314, is cited here as a reference predicate device for materials and general design shape.

8 PERFORMANCE DATA

This 510(k) submission provided performance data to establish the substantial equivalence of the Elite SPK and Compasso to the predicate devices. The following is a summary of the performance data.

Sterilization and Shelf Life: The devices are sterilized using standard methods and the sterilization cycles have been validated following international standards. The shelf life of the devices has been established through stability studies.

Biocompatibility: Biocompatibility evaluation has been performed to show the device materials are safe, biocompatible and suitable for their intended use. Both ISO 10993 and FDA Draft Guidance “Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” have been taken into account to evaluate the biocompatibility of the device materials.

Performance Testing: Performance testing was performed to evaluate the fixation strength of the Elite SPK compared to the predicate device. These tests showed that the Elite SPK has adequate fixation strength and is comparable to the predicate devices.

The performance data demonstrate that the Elite SPK and Compasso are substantially equivalent to the predicate devices.