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

January 6, 2016

Spineart
Mr. Franck Pennesi
International Center Cointrin
20 Route de Pre-bois – CP 1813
1215 GENEVA 15
Switzerland

Re: K151104
Trade/Device Name: OTELO LL
Regulation Number: 21 CFR 878.4800
Regulation Name: Retractor
Regulatory Class: Class I
Product Code: GAD
Dated: December 2, 2015
Received: December 4, 2015

Dear Mr. Pennesi:

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,

William J. Heetderks -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K151104

Device Name
OTELO LL Retractor

Indications for Use *(Describe)*

The OTELO LL Retractor is intended to provide the surgeon access to the spine by dissection and traction of soft and bony tissue

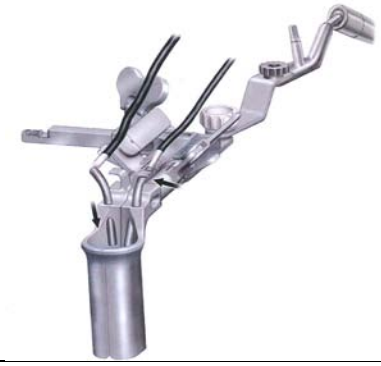
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

510k	TRADITIONAL
Basis for submission	New devices
Submitted by	SPINEART International Center Cointrin 20 route de pré-bois CP1813 1215 GENEVA 15 SWITZERLAND
Contacts	Franck PENNESI Director of Industry & Quality Phone : +41 22 570 1246 Fax : +41 22 799 4026 Mail : fpennesi@spineart.com Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr
Date Prepared	January 5, 2016
Common Name	Retractor
Trade Name	OTELO® LL
Classification Name	Retractor
Regulation description	Manual surgical instrument for general use.
Class	I
Product Code	GAD
CFR section	878.4800
Device panel	General & Plastic Surgery
Legally marketed predicate devices	Primary predicate: Quadrant Retractor System (K043602) manufactured by Medtronic Sofamor Danek

Design features	OTELO LL retractor by SPINEART	MAST QUADRANT Retractor system by Medtronic
510(k) #	Present submission	K043602
Product code	GAD	GAD
Pictures		
21 CFR	878.4800	878.4800
Common name	Retractor, Manuel Surgical Instrument	Retractor, Manuel Surgical Instrument

Design features	OTELO LL retractor by SPINEART	MAST QUADRANT Retractor system by Medtronic
Indications for use	The OTELO®LL Retractor is intended to provide the surgeon access to the spine by dissection and traction of soft and bony tissue.	The MAST QUADRANT™ Retractor System is intended to provide surgeons with instruments such as dilators, retractors, light sources and pedicle access needles used to perform a variety of spinal fixation procedures utilizing a minimally invasive approach. The MAST QUADRANT ™ Retractor System is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervical, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the MAST QUADRANT™ Retractors and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants.
Description	The OTELO®LL Retractor System is a tubular-based retraction system, designed to provide surgeons with the freedom to retract tissue through any combination of distracting or articulating the blades. The OTELO®LL Retractor System includes instruments used to access the spine by dilating the overlying tissues, as well serving as a retracting device to maintain the access. The system can be used in conjunction with microscopes, light sources, cameras, or other visualization aids.	The MAST QUADRANT™ Retractor System is a tubular-based retraction system, designed to provide surgeons with the freedom to retract tissue through any combination of distracting or articulating the blades. The MAST QUADRANT ™ System includes instruments used to access the spine by dilating the overlying tissues, as well serving as a retracting device to maintain the access. The system can be used in conjunction with microscopes, light sources, cameras, or other visualization aids.
Material	Stainless Steel, PEEK and PEEK Carbon.	Stainless Steel
Design features	Self-locking mechanism and minimal invasive use	Self-locking mechanism and minimal invasive use
Operating principle	Gives surgeons an easy access and good visualization of the disc to be treated.	Gives surgeons an easy access and good visualization of the disc to be treated.
Technological characteristics	The retractor system is composed of one retractor base associated to different instruments such as dilators tube, blades, wires, retractor, shim pins, light source and flex arm attachment. Range of blades is composed of 10 right, 10 left and 10 posterior blades which varies from 90 to 180 mm length. If needed, a fourth blade distraction system can be adapted in order to increase surgeon's access visibility. This complementary system is composed of 2 wide and 2 narrow supplemental blades which varies from 5 to 10 mm width.	The retractor system is composed of one retractor base associated to different instruments such as dilators tube, blades, wires, retractor, light source and flex arm attachment. Range of blades is composed of 5 right and 5 left blades which varies from 40 to 80 mm length. If needed, a complementary medial /lateral distraction system can be adapted in order to increase surgeon's access visibility. This complementary system is composed of 3 wide and 3 narrow supplemental blades which varies from 50 to 90 mm length.

Design features	OTELO LL retractor by SPINEART	MAST QUADRANT Retractor system by Medtronic
Ranges of the retractor opening distance	Antero-posterior opening range: 21 mm to 46 mm Cranial-caudal opening range: 21 mm to 100 mm	Cranial-caudal opening range: 30 mm to 52 mm
Ranges of blade angle	Cranial-Caudal inclination angle range: 0° to +15°	/
Packaging	Instruments are individually packaged in polyethylene sealed pouch with label and IFU included. When packaged as an Instrument set, the set is packaged in polyethylene sealed pouch with label and IFU included.	Same for non sterile instruments.
Shelf life	Not applicable. Devices are provided non sterile.	/
Sterilization	Steam sterilization	Steam sterilization
Biocompatibility	Meets ISO 10993	Meets ISO 10993

Pre-clinical verification and validation tests results:

Test	**Results**	**Conclusions**
ISO MTS Cytotoxicity. Report n° 199740	Percentage viability of test article: 86.4%	No cytotoxic potential
ISO Intracutaneous Study in Rabbits - Two Extracts. Report n° 199741	The 0.9% NaCl extract of the test article did not induce any erythema or edema reactions after injection by intracutaneous route in the rabbit. The sesame oil extract of the test article did not induce more erythema and edema reactions than the vehicle alone after injection by intracutaneous route in the rabbit.	No erythema or edema reactions
ISO Acute Systemic Toxicity Study in Mice - Two Extracts. Report n° 199743	No body weight loss greater than 10% occurred, no abnormal behaviour was noted and body weight gains were thereafter observed until the end of the study. All animals appeared clinically normal at the beginning and throughout the study.	No evidence of significant systemic toxicity or mortality
ISO Guinea Pig Maximization Sensitization Test - Two Extracts. Report n° 199742	0.9% NaCl extract: sensitization grade 0 Sesame oil extract: sensitization grade 0 All animals appeared clinically normal throughout the study.	The test article was not considered a sensitizer in the guinea pig maximization model
Validation of the Manual Cleaning Process According to the ISO 17664 standard and the AAMI TIR 30 Technical Report. Report n° 199900	No soil was observed. No protein (<6.4 µg/cm^2) was detected. No hemoglobin (<2.2 µg/cm^2) was detected.	The manual cleaning process is validated.
Validation of the Automated Cleaning Process According to the ISO 17664 standard and the AAMI TIR 30 Technical Report. Report n° 200220	No soil was observed. No protein (<6.4 µg/cm^2) was detected. No hemoglobin (<2.2 µg/cm^2) was detected.	The automated cleaning process is validated.
Steam sterilization Study for the SPINEART OTELO Retractor Set. Report n° 154535-002 rev 1	Sterilization Parameters (132° 2') provide a SAL not less than 10^{-6}. No moisture was observed after dry time of 30'.	Steam sterilization parameters 132°C, 4'and dry time 30' are validated.

Mechanical performances - Verification Test report n°VRR67-01-00	Minimal opening of 100 mm is obtained. No breakage of the blades. No disassembly of the blades and the retractor. No disassembly of the arms of the retractor. No breakage or damage of the teeth of the rack. No breakage or damage of the thread feature of the knobs. Minimal opening of 46 mm is obtained. No breakage or damage of the thread feature of the knobs. No rotation or malfunction of the 4th blade assembly. No disassembly of the shim pin from the shim tool. No disassembly of the shim pin from the blade.	Mechanical characteristics are conform to the needs.
Functionality performances - Validation Test report n°VLR67-08-00	The light system worked well. Radiolucency is a clear advantage of the system. The arm, the base arm and the attachment worked well. It has been commented that the arm attachment should be connected to the arm before attaching to the retractor body. The multi-function double hex driver was well appreciated for the posterior blade manipulation. The ratcheting mechanism and the toe-ing of the blades worked well. The 4th blade attachment is well designed. Posterior Shim and Shim pin worked correctly.	Functionality is conform to the needs.

Discussion:

Differences of technical characteristics between subject device and predicate device:
The main differences between the two systems are limited to:

- the material used for blades (CF/PEEK for OTELO versus stainless steel for predicate device),
- the length of the range of blades (90 to 150 mm for OTELO versus 40 to 80 mm for predicate device),
- the complementary distraction system that can be used to increase surgeon 's visibility access,
- the cranial-caudal opening range (21 mm to 100 mm for OTELO versus 30 to 52 for predicate device).

Safety and effectiveness:
Material: Based on pre-clinical biocompatibility verification tests (reports n°199740, 199741, 199742 and 199743), it has been demonstrated that CF/PEEK material is conforming to ISO 10993-1 for contact inferior to 24 hours.

Length of blade: longer blades (90 to 180 mm) have been designed in order to provide a lateral access to the spine. Based on pre-clinical mechanical verification tests (report n°VRR67-01-00) and pre-clinical validation test (report n° VLR67-08-00), it has been demonstrated that mechanical characteristics for OTELO is conforming to the needs and indications for use.

Complementary distraction system: Based on pre-clinical mechanical verification tests (report n°VRR67-01-00) and pre-clinical validation test (report n° VLR67-08-00), it has been demonstrated

that mechanical characteristics of the complementary system for OTELO is conforming to the needs and indications for use.

Cranial-caudal opening: Based on pre-clinical mechanical verification tests (report n°VRR67-01-00) and pre-clinical validation test (report n° VLR67-08-00), it has been demonstrated that mechanical characteristics for OTELO is conforming to the needs and indications for use.

Conclusion:

The significant differences between the OTELO retractor system and the other mentioned marketed system which would adversely affect the safety and performances of the product have been tested in order to demonstrate OTELO capabilities.

The Spineart OTELO retractor system is substantially equivalent in design, function, mechanical performances and intended use, to the existing previously cleared spinal devices, MAST QUADRANT Retractor System by Medtronic Sofamor Danek (K043602).