DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 8, 2017

Nuvasive Specialized Orthopedics, Inc
% Ms. Cora Sim
Associate Manager, Regulatory Affairs
Nuvasive Specialized Orthopedics, Inc;
101 Enterprise
Aliso Viejo, California 92656

Re: K170939
Trade/Device Name: Supplemental Instrument Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: July 18, 2017
Received: July 19, 2017

Dear Cora Sim:

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,

Tara A. Ryan -S

for
Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*

K170939

Device Name
NSO Supplemental Instrument Trays

Indications for Use *(Describe)*

The N S O Supplemental Instrument Trays are intended to organize, protect, and transport instruments during steam sterilization and subsequent storage. NSO Supplemental Instrument Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated FDA cleared sterilization wrap in order to maintain sterility of the enclosed medical instruments. The following sterilization cycle is to be used:

Pre-vacuum Steam Sterilization parameters: 132°C for 4 minutes with 40 minutes dry time

The validated worst case loading configuration (non-stacked) for the Supplemental Instrument Trays included the following worst case lumen dimension and maximum weight for each of the trays:

Tray	Model	Dimensions (Inner Diameter x Length)	Number of Lumens	Maximum Weight (lbs.)
Supplemental Instrument Tray	SIT1-000	0.146" x 10.75"	1	10.0
Supplemental Reamer Tray	SRT1-000	0.125" x 18.4"	1	13.1
Flexible Reamer Tray	SRT2-000	0.096" x 19.314"	1	14.4

List of Devices:

Tray	Model	Dimensions (Length x Width x Depth)	Validated Weight of Tray with Instruments
Supplemental Instrument Tray	SIT1-000	510mm x 250mm x 45mm	10.0 lbs
Supplemental Reamer Tray	SRT1-000*	510mm x 250mm x 87mm	13.1 lbs*
Flexible Reamer Tray	SRT2-000‡	510mm x 250mm x 87mm	14.4 lbs‡

*Includes insert tray with dimensions 497mm x 240mm x 52mm.
‡Includes insert tray with dimensions 490mm x 240mm x 52mm.

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.

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NSO Supplemental Instrument Trays
510(k) Summary – K170939
August 7, 2017

1.	**Company:**	NuVasive Specialized Orthopedics, Inc. 101 Enterprise, Suite 100 Aliso Viejo, CA 92656
	Contact:	Cora Sim Associate Manager, Regulatory Affairs Phone: (949) 544-6478 Fax: (949) 837-3664
	Date Summary Prepared:	**August 7, 2017**
2.	**Proprietary Trade Name:**	NSO Supplemental Instrument Trays
3.	**Classification Name:**	Sterilization Wrap Containers, Trays, Cassettes, & other Accessories (21 CFR 880.6850)
4.	**Product Code:**	KCT (Sterilization Tray)
5.	**Device Classification:**	Class II
6.	**Predicate Device:**	NSO Supplemental Instrument Trays (K151594)

7. **Indications for Use:** The NSO Supplemental Instrument Trays are intended to organize, protect, and transport instruments during steam sterilization and subsequent storage. NSO Supplemental Instrument Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated FDA cleared sterilization wrap in order to maintain sterility of the enclosed medical instruments. The following sterilization cycle is to be used:

Pre-vacuum Steam Sterilization parameters: 132°C for 4 minutes with 40 minutes dry time

The validated worst case loading configuration (non-stacked) for the NSO Supplemental Instrument Trays included the following worst case lumen dimension and maximum weight for each of the trays:

Tray	Model	Lumen Dimensions (Inner Diameter x Length)	Number of Lumens	Maximum Tray Weight (lbs.)
Supplemental Instrument Tray	SIT1-000	0.146" x 10.75"	1	10.0
Supplemental Reamer Tray	SRT1-000	0.125" x 18.4"	1	13.1*
Flexible Reamer Tray	SRT2-000	0.096" x 19.314"	1	14.4‡

List of Devices:

Tray	Model	Dimensions (Length x Width x Depth)	Validated Weight of Tray with Instruments
Supplemental Instrument Tray	SIT1-000	510mm x 250mm x 45mm	10.0 lbs
Supplemental Reamer Tray	SRT1-000*	510mm x 250mm x 87mm	13.1 lbs*
Flexible Reamer Tray	SRT2-000‡	510mm x 250mm x 87mm	14.4 lbs‡

*Includes insert tray with dimensions 497mm x 240mm x 52mm.
‡Includes insert tray with dimensions 490mm x 240mm x 52mm.

8. **Device Description:** The NSO Supplemental Instrument Trays are comprised of a Supplemental Instrument Tray, a Supplemental Reamer Tray, and a Flexible Reamer Tray. These trays are designed to organize, protect, and transport instruments during steam sterilization and subsequent storage. The trays are composed of a lid and base tray with handles and are perforated for steam penetration. The Supplemental Instruments within the trays are composed of Flexible Reamers, Quick Connect Adaptors, an Intraoperative X-Ray Ruler, a Direct AO Depth Gauge, a Diamond Point Awl, a Guide Wire Chuck, a Soft Tissue Protector – Paddle, a Soft Tissue Protector – Tube, a Teardrop Cannulated Driver, a Screw Gauge, and a Guide Wire Pusher. The Supplemental Instrument Tray has the following approximate external dimensions: 510 mm (length) x 250 mm (width) x 45 mm (depth). The Supplemental Reamer and Flexible Reamer Tray have the following external dimensions: 510 mm (length) x 250 mm (width) x 87 mm (depth). An insert tray is used with the Supplemental Reamer and Flexible Reamer Tray. The insert tray for the Supplemental Reamer Tray has the following dimensions: 497 mm (length) x 240 mm (width) x 52 mm (depth). The insert tray for the Flexible Reamer Tray has the following dimensions: 490 mm (length) x 240 mm (width) x 52 mm (depth). The Supplemental Instrument Trays are reusable and are used to store instruments prior to, during, and after the sterilization process. The trays are made of anodized aluminum and have medical grade, Class VI Silicone instrument holders with stainless steel mounting hardware which are used to secure, separate, and organize the instruments within the trays. The tray handles are also encased in medical grade, Class VI Silicone.

The type of instruments and maximum number of instruments for each of the sterilization trays listed above are as follows:

Supplemental Instrument Tray (SIT1-000):

Model Number	Instrument Description	Quantity
DPA1-000	11mm DIAMOND POINT AWL	1
DGA1-000	DIRECT AO DEPTH GAUGE	1
GWC1-000	GUIDE WIRE CHUCK	1
STP1-000	SOFT TISSUE PROTECTOR - PADDLE	1
STT1-000	SOFT TISSUE PROTECTOR - TUBE	1
XRR1-000	INTEROPERATIVE X-RAY RULER	1
TCD1-000	TEARDROP CANNULATED DRIVER	1
PSG1-000	SCREW GAUGE	1
GWP1-000	GUIDE WIRE PUSHER	1
Maximum number of instruments		9

Supplemental Reamer Tray (SRT1-000):

Model Number	Instrument Description	Quantity
RMR1-070	REAMER - 7.0MM	1
RMR1-075	REAMER - 7.5MM	1
RMR1-080	REAMER - 8.0MM	1
RMR1-085	REAMER - 8.5MM	1
RMR1-090	REAMER - 9.0MM	1
RMR1-095	REAMER - 9.5MM	1
RMR1-100	REAMER - 10.0MM	1
RMR1-105	REAMER - 10.5MM	1
RMR1-110	REAMER - 11.0MM	1
RMR1-115	REAMER - 11.5MM	1
RMR1-120	REAMER - 12.0MM	1
RMR1-125	REAMER - 12.5MM	1
RMR1-130	REAMER - 13.0MM	1
RMR1-135	REAMER - 13.5MM	1
RMR1-140	REAMER - 14.0MM	1
RMR1-145	REAMER - 14.5MM	1
RMR1-150	REAMER - 15.0MM	1
LQC1-000	LARGE AO QUICK CONNECT	1
Maximum number of instruments		18

Flexible Reamer Tray (SRT2-000):

Model Number	Instrument Description	Quantity
T18151	FLEXIBLE REAMER - 7.0MM	1
T18152	FLEXIBLE REAMER - 7.5MM	1
T18153	FLEXIBLE REAMER - 8.0MM	1
T18154	FLEXIBLE REAMER - 8.5MM	1
T18155	FLEXIBLE REAMER - 9.0MM	1
T12065	FLEXIBLE REAMER - 9.5MM	1
T12066	FLEXIBLE REAMER - 10.0MM	1

T12067	FLEXIBLE REAMER - 10.5MM	1
T12068	FLEXIBLE REAMER - 11.0MM	1
T12069	FLEXIBLE REAMER - 11.5MM	1
T12070	FLEXIBLE REAMER - 12.0MM	1
T12071	FLEXIBLE REAMER - 12.5MM	1
T12072	FLEXIBLE REAMER - 13.0MM	1
T18156	FLEXIBLE REAMER - 13.5MM	1
T18157	FLEXIBLE REAMER - 14.0MM	1
T18158	FLEXIBLE REAMER - 14.5MM	1
T18159	FLEXIBLE REAMER - 15.0MM	1
LQC2-000	LARGE AO QUICK CONNECT	1
Maximum number of instruments		18

After sterilization of NSO Supplemental Instrument Trays, a minimum cooling time of 30 minutes is recommended prior to removing or handling the instrument trays.

9. **Technological Characteristics:** Substantial equivalence is based on identical intended use, design, technological characteristics, materials of composition, and principles of operation. The Flexible Reamer Tray subject of this 510(k) submission is identical to the NSO Supplemental Instrument Trays. The additional tray that is subject of this premarket notification and the predicate device have the same intended use. Specifically, both the predicate NSO Supplemental Instrument Trays and the Flexible Reamer Tray that is subject of this submission are intended to store various reusable instruments in order to organize, protect, and transport instruments during steam sterilization and subsequent storage. The additional tray is available in the same dimensions, materials, and configuration as the predicate NSO Supplemental Instrument Trays. No changes are being made to the materials, technological characteristics, or principles of operation as a result of this premarket notification. The trays are composed of a lid and base tray with handles and are perforated for steam penetration. The additional Flexible Reamer Tray subject of this submission is substantially equivalent to the NSO Supplemental Instrument Trays cleared in K151594.

Device Comparison Table for Substantial Equivalence:

Feature	Predicate NSO Supplemental Instrument Trays	Subject NSO Supplemental Instrument Trays
510(k) Number	K15194	K170939
Product Code	KCT	KCT
Intended Use	The NSO Supplemental Instrument Trays intended to organize, protect, and transport instruments during steam sterilization and subsequent storage.	Same

Design	The lid, base tray, and insert tray are composed of anodized aluminum. An internal individual insert tray is utilized by the Supplemental Reamer Tray. Medical grade Class VI Silicone instrument holders and with stainless steel mounting hardware are used to secure, separate, and organize the instruments within the trays.	Same
Dimensions	Supplemental Instrument Tray: Base tray: 510mm (length) x 250mm (width) x 45mm (depth) Supplemental Reamer Tray: Base tray: 510mm (length) x 250mm (width) x 87mm (depth) Insert Tray: 497 mm (length) x 240 mm (width) x 52 mm (depth)*	Flexible Instrument Tray: Base tray: Same as Supplemental Reamer Tray Insert Tray: 490 mm (length) x 240 mm (width) x 52 mm (depth)*
Material composition	Anodized aluminum, Stainless Steel, Silicone	Same
Physical Properties	Evenly distributed perforated hole pattern.	Same
Sterilization Method	Steam	Same
Sterilant Penetration	Sterilant (steam) penetration through perforations in tray.	Same
Sterilization cycle	Pre-vacuum	Same
Exposure Temperature	132° C	Same
Exposure time	4 minutes	Same
Dry Time	40 minutes	Same
Air permeance	Yes	Same
Diameter of each perforation	0.197 inches	Same
Number of perforations	Supplemental Instrument Tray: Tray Lid: 916 Base Tray: 871 Supplemental Reamer Tray: Tray Lid: 916 Base Tray: 956 Insert Tray: 948	Flexible Reamer Tray: Tray Lid: Identical Base Tray: Same as Supplemental Reamer Tray Insert Tray: 931
Vent to volume ratios	Supplemental Instrument Tray: 0.192 in^{-1} Supplemental Reamer Tray: 0.147 in^{-1}	Flexible Reamer Tray: Same as Supplemental Reamer Tray

Material compatibility with sterilization process	The materials used in the NSO Supplemental Instrument Trays were exposed to 100 sterilization cycles and no material degradation was observed. All materials maintained their integrity and remained fully functional. Performance testing demonstrated that the materials of construction are compatible with steam sterilization.	Same
Toxicological properties	Extracts of test article (polymeric component) on L-939 mouse fibroblast cells in MEM elution assay did not display a cytotoxic response and is considered non-cytotoxic. Testing demonstrated that the materials of construction are biocompatible.	Same
Results of transportation studies	Shipping validation was performed on the NSO Supplemental Instrument Trays. The package performance testing results demonstrated all acceptance criteria were met.	Same
Summary of cleaning validation information	The NSO Supplemental Instrument Trays have been validated to be cleaned using both a manual and automated process. Hemoglobin, Micro BCA protein, and TOC test results met all acceptance criteria.	Same
Limitations of reprocessing	The function and physical construction of the NSO Supplemental Instrument Trays and their components are safe and effective after exposure to 100 sterilization cycles. The end of tray life is determined through the inspection of each tray after the required cleaning and sterilization cycles. The life of the trays are limited only by irreparable physical damage from mishandling.	Same

Summary of drying time validation	The dry time validation was successful in determining an effective dry time of 40 minutes for the validated pre-vacuum steam sterilization cycle. Acceptance criteria below were met during validation of the dry time: 1) Autoclave data showing appropriate dwell time at 132°C (+3°C) for each full cycle 2) Confirmation of the absence of moisture on the trays and sterilization wrap 3) No more than 3% difference in weight prior to and after sterilization	Same

*For use with the Reamer Tray

10. **Performance Data:** Since the Flexible Reamer Tray contains instruments with a worst case dimension (smaller lumen diameter and longer length) compared to the NSO Supplemental Instrument Trays, non-clinical performance testing was conducted to establish substantial equivalence of the Flexible Reamer Tray to the predicate device. Sterilization validation testing was conducted to confirm that a sterility assurance level (SAL) of 10^{-6} was achieved at the validation sterilization parameter in the pre-vacuum steam sterilization cycle according to ISO 17665-1 and AAMI TIR12. A dry time validation was performed and was successful in determining an effective dry time of 40 minutes for the validated pre-vacuum steam sterilization cycle. The cleaning and sterilization validation study demonstrated that the previously validated cleaning and sterilization parameters for the predicate NSO Supplemental Instrument Trays were effective and will adequately clean and sterilize the Flexible Reamer Tray. No changes are being made to the design or materials of the NSO Supplemental Instrument Trays; therefore, testing with regard to biocompatibility and limits of reprocessing was not repeated and the original testing results are still applicable. Results of the testing demonstrated that the device is safe and effective for its intended use.

11. **Conclusion:** Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, the subject NSO Supplemental Instrument Trays are as safe and as effective as, the legally marketed predicate device, Ellipse Supplemental Instrument Trays cleared under K151594 under regulation 21 CFR 880.6850, product code KCT.