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

August 28, 2015

NuVasive, Inc.
Ms. Olga Lewis
Regulatory Affairs Lead Specialist
7475 Lusk Blvd.
San Diego, CA 92121

Re: K143579
Trade/Device Name: NuVasive® Sterilization Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: July 23, 2015
Received: July 24, 2015

Dear Ms. Lewis:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)*
K143579

Device Name
NuVasive® Sterilization Trays

Indications for Use *(Describe)*
The NuVasive Sterilization Trays are intended to contain NuVasive implants and surgical instruments for sterilization, storage and handling. The NuVasive Sterilization Trays are suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The 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 devices.
Sterilization validations for three level worst case tray (20.5" x 10" x 7.375") included three different loading configurations: implant only content (26.4 lbs.), instrument only content (39.95 lbs.) and mixed instruments and implants content (30.45 lbs.)
Validated worst case loading configurations included 23 instruments with lumens including the following worst case lumen dimensions:
- 1.6 mm x 306.8 mm
- 1.1 mm x 166.4 mm
- 7.2 mm x 331.9 mm
- 5.5 mm x 356.9 mm

Do not exceed a maximum load of 25 lbs in the sterilization tray.
Validated sterilization parameters for NuVasive Sterilization Trays:

Method: Steam
Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Minimum Dry Time: 30 minutes
Minimum Cool Down Time: 40 minutes

List of Devices:

FOOTPRINT	MODEL	DIMENSIONS (L x W x H)
Footprint 1	1-1	6.0" x 3.3" x 2.2"
	1-2	6.5" x 3.5" x 2.0"
Footprint 2	2-1	8.0" x 4.3" x 1.6"
	2-2	8.0" x 6.0" x 3.5"
Footprint 3	3-1	19.8" x 9.4" x 2.0"
	3-2	20.0" x 10.0" x 2.0"
	3-3	20.0" x 10.0" x 6.5"
	3-4	20.0" X 9.5" X 1.8"
	3-5	*20.0" x 9.5" x 2.0"*
	3-6	20.0" x 9.5" x 2.5"
	3-7	20.0" x 9.5" x 3.0"
	3-8	20.0" x 9.5" x 3.5"
	3-9	20.0" x 9.5" x 4.0"
	3-10	20.0" x 9.5" x 4.5"
	3-11	20.0" x 9.5" x 5.5"
	3-12	20.0" x 9.5" x 6.8"
	3-13	20.0" x 9.6" x 2.0"
	3-14	20.0" x 9.8" x 6.3"
	3-15	20.1" x 9.4" x 2.5"
	3-16	20.4" x 9.6" x 3.0"
	3-17	20.5" x 10.0" x 2.0"
	3-18	20.5" x 10.0" x 3.0"
	3-19	20.5" x 10.0" x 4.0"
	3-20	20.5" x 10.0" x 5.0"
	3-21	20.5" x 10.0" x 6.0"
	3-22	20.5" x 9.5" x 5.0"
	3-23	20.5" x 9.5" x 5.1"
	3-24	20.5" x 9.5" x 5.6"
	3-25	20.5" x 9.5" x 6.1"
	3-26	20.5" x 9.5" x 6.3"
	3-27	20.5" x 9.5" x 6.4"
	3-28	20.5" x 9.5" x 6.6"
	3-29	20.5" x 9.5" x 7.0"
	3-30	20.5" x 9.7" x 2.0"
	3-31	20.5" x 9.7" x 3.8"
	3-32	20.5" x 9.7" x 5.2"
	3-33	20.5" x 9.8" x 2.0"
	3-34	20.5" x 9.8" x 2.1"
	3-35	20.5" x 9.8" x 2.2"
	3-36	20.5" x 9.8" x 2.3"
	3-37	20.5" x 9.8" x 2.5"

FOOTPRINT	MODEL	DIMENSIONS (L x W x H)
Footprint 3	3-38	20.5" x 9.8" x 3.0"
	3-39	20.5" x 9.8" x 3.1"
	3-40	20.5" x 9.8" x 3.3"
	3-41	20.5" x 9.8" x 3.5"
	3-42	20.5" x 9.8" x 3.6"
	3-43	20.5" x 9.8" x 3.7"
	3-44	20.5" x 9.8" x 3.8"
	3-45	20.5" x 9.8" x 3.9"
	3-46	20.5" x 9.8" x 4.0"
	3-47	20.5" x 9.8" x 4.1"
	3-48	20.5" x 9.8" x 4.3"
	3-49	20.5" x 9.8" x 4.4"
	3-50	20.5" x 9.8" x 4.5"
	3-51	20.5" x 9.8" x 4.6"
	3-52	20.5" x 9.8" x 4.7"
	3-53	20.5" x 9.8" x 4.8"
	3-54	20.5" x 9.8" x 5.0"
	3-55	20.5" x 9.8" x 5.3"
	3-56	20.5" x 9.8" x 5.5"
	3-57	20.5" x 9.8" x 5.7"
	3-58	20.5" x 9.8" x 6.0"
	3-59	20.5" x 9.8" x 6.1"
	3-60	20.5" x 9.8" x 6.3"
	3-61	20.5" x 9.8" x 6.6"
	3-62	20.5" x 9.8" x 7.1"
	3-63	20.5" x 9.8" x 7.2"
	3-64	20.6" x 9.7" x 3.4"
	3-65	20.6" x 9.7" x 3.6"
	3-66	20.6" x 9.7" x 4.4"
	3-67	20.6" x 9.7" x 4.7"
	3-68	20.8" x 9.8" x 2.8"
	3-69	20.8" x 9.8" x 5.2"
	3-70	20.9" X 10.0" X 2.3"
	3-71	20.9" x 9.8" x 6.6"
	3-72	21.0" x 10.0" x 4.0"
	3-73	21.0" x 10.0" x 4.2"
	3-74	21.0" x 10.0" x 4.3"
	3-75	21.0" x 10.0" x 6.0"
	3-76	21.0" x 10.1" x 3.1"
	3-77	21.0" x 9.7" x 3.0"
	3-78	21.0" x 9.7" x 3.7"

FOOTPRINT	MODEL	DIMENSIONS (L x W x H)
Footprint 3	3-79	21.0" x 9.7" x 4.2"
	3-80	21.0" x 9.7" x 4.3"
	3-81	21.0" x 9.7" x 4.8"
	3-82	21.0" x 9.7" x 6.2"
	3-83	21.0" x 9.7" x 6.8"
	3-84	21.0" x 9.8" x 2.2"
	3-85	21.0" x 9.8" x 3.5"
	3-86	21.0" x 9.8" x 3.8"
	3-87	21.0" x 9.8" x 4.0"
	3-88	21.0" x 9.8" x 5.6"
	3-89	21.1" x 9.7" x 3.7"
	3-90	21.1" x 9.7" x 6.2"
	3-91	21.1" x 9.7" x 6.4"
	3-92	21.1" x 9.8" x 4.6"
	3-93	21.1" x 9.8" x 6.0"
	3-94	21.2" x 10.0" x 4.5"
	3-95	21.2" x 10" x 5.2"
	3-96	21.2" x 9.7" x 4.8"
	3-97	21.2" x 9.7" x 4.9"
	3-98	21.2" x 9.7" x 5.4"
	3-99	21.3" x 10.0" x 4.9"
	3-100	21.3" x 10.0" x 6.0 "
	3-101	21.3" x 10.1" x 5.8"
	3-102	21.3" x 8.5" x 5.3"
	3-103	21.4" x 10.0" x 4.5"
	3-104	21.4" x 10.0" x 5.0"
	3-105	21.4" x 10.0" x 6.0"
	3-106	21.4" x 10.1" x 2.9"
	3-107	21.4" x 10.1" x 3.0"
	3-108	21.4" x 10.1" x 3.5"
	3-109	21.4" x 10.1" x 3.7"
	3-110	21.4" x 10.1" x 3.8"
	3-111	21.4" x 10.1" x 4.6"
	3-112	21.4" x 10.1" x 4.7"
	3-113	21.4" x 10.1" x 5.3"
	3-114	21.4" x 10.1" x 6.4"
	3-115	21.4" x 10.1" x 6.8"
	3-116	21.4" x 10.1" x 7.0"
	3-117	21.4" x 9.6" x 5.0"
	3-118	21.4" x 9.6" x 6.0"
	3-119	21.4" x 9.6" x 6.4"
Footprint 3	3-120	21.5" x 10.0" x 3.0"
	3-121	21.5" x 10.0" x 3.8"
	3-122	21.5" x 10.0" x 4.6"
	3-123	21.6" x 9.8" x 4.2"
	3-124	21.6" x 9.9" x 3.0"
	3-125	21.7" x 10.0" x 3.1"
	3-126	21.7" x 9.9" x 4.1"
	3-127	21.7" x 9.9" x 5.0"
	3-128	21.7" x 9.9" x 6.3"
	3-129	21.8" x 10.4" x 4.1"
	3-130	21.8" x 10.5" x 4.7"
	3-131	21.9" x 10.0" x 3.2"
	3-132	21.9" x 10.0" x 3.5"
	3-133	21.9" x 10.0" x 6.0"
	3-134	22.0" x 9.7" x 6.2"
	3-135	22.0" x 10.0" x 6.6"
Footprint 4	4-1	9.0" x 6.5" x 2.5"
	4-2	9.8" x 6.3" x 3.6"
	4-3	9.8" x 8.3" x 2.1"
	4-4	9.8" x 9.0" x 3.5"
	4-6	9.9" x 7.8" x 2.0"
Footprint 5	5-1	10.0" x 10.0" x 2.0"
	5-2	10.0" x 10.0" x 2.3"
	5-3	10.4" x 9.8" x 2.1"
	5-4	10.4" x 9.8" x 2.3"
	5-5	10.4" x 9.8" x 2.5"
	5-6	10.4" x 9.8" x 3.0"
	5-7	10.6" x 10.0" x 3.5"
	5-8	10.6" X 9.7" X 2.9"
	5-9	10.6" X 9.7" X 3.6"
Footprint 6	6-1	12.3" x 8.3" x 2.1"
	6-2	13.3" x 9.3" x 2.1"
	6-3	14.5" x 9.8" x 2.3"
Footprint 7	7-1	15.0" x 10.0" x 2.5"
	7-2	15.8" x 9.8" x 5.2"
	7-3	16.8" x 9.8" x 3.2"
Footprint 8	8-1	15.7" x 4.7" x 2.7"
	8-2	15.8" x 4.5" x 2.5"

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Olga Lewis
Regulatory Affairs Lead Specialist
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: August 25, 2015

B. Device Name

Trade or Proprietary Name:	*NuVasive® Sterilization Trays*
Common or Usual Name:	Sterilization Trays, Instrument Tray
Classification Name:	Sterilization wrap containers, trays, cassettes & other accessories
Classification:	Class II; 21 CFR § 880.6850
Product Code:	KCT

C. Predicate Devices

The subject *NuVasive Sterilization Trays* are substantially equivalent to the primary predicate device, *Skeletal Dynamics Sterilization Trays* (K102103).

D. Device Description

The NuVasive Sterilization Trays are designed to contain NuVasive implants and instruments for sterilization, storage, and handling, and to allow optimal exposure of the tray's content to steam during the sterilization process. The trays are intended only for use with NuVasive medical devices. The trays must be used in conjunction with an FDA cleared sterilization wrap in order to maintain sterility of the contents.

The trays are different sizes of the same basic configuration and consist of a rectangular base with a lid that fastens to the base with latches. The trays have perforations on the lid, base bottom and sides. Insert trays with custom made brackets can be used to organize instruments and hold caddies in which smaller components are stored. The insert trays and caddies also contain perforations to allow optimal exposure of the tray's contents to sterilant during the sterilization process.

E. Indications for Use

The NuVasive Sterilization Trays are intended to contain NuVasive implants and surgical instruments for sterilization, storage and handling. The NuVasive Sterilization Trays are suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The 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 devices.

Sterilization validations for three level worst case tray (20.5" x 10" x 7.375") included three different loading configurations: implant only content (26.4 lbs.), instrument only content (39.95 lbs.) and mixed instruments and implants content (30.45 lbs.)
Validated worst case loading configurations included 23 instruments with lumens including the following worst case lumen dimensions:

- 1.6 mm x 306.8 mm
- 1.1 mm x 166.4 mm
- 7.2 mm x 331.9 mm
- 5.5 mm x 356.9 mm

Do not exceed a maximum load of 25 lbs in the sterilization tray.
Validated sterilization parameters for NuVasive Sterilization Trays:

Method: Steam
Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Minimum Dry Time: 30 minutes
Minimum Cool Down Time: 40 minutes

List of Devices:

FOOTPRINT	MODEL	DIMENSIONS (L x W x H)
Footprint 1	1-1	6.0” x 3.3” x 2.2”
	1-2	6.5” x 3.5” x 2.0”
Footprint 2	2-1	8.0” x 4.3” x 1.6”
	2-2	8.0” x 6.0” x 3.5”
Footprint 3	3-1	19.8” x 9.4” x 2.0”
	3-2	20.0” x 10.0” x 2.0”
	3-3	20.0” x 10.0” x 6.5”
	3-4	20.0” X 9.5” X 1.8”
	3-5	*20.0” x 9.5” x 2.0”*
	3-6	20.0” x 9.5” x 2.5”
	3-7	20.0” x 9.5” x 3.0”
	3-8	20.0” x 9.5” x 3.5”
	3-9	20.0” x 9.5” x 4.0”
	3-10	20.0” x 9.5” x 4.5”
	3-11	20.0” x 9.5” x 5.5”
	3-12	20.0” x 9.5” x 6.8”
	3-13	20.0” x 9.6” x 2.0”
	3-14	20.0” x 9.8” x 6.3”
	3-15	20.1” x 9.4” x 2.5”
	3-16	20.4” x 9.6” x 3.0”
	3-17	20.5” x 10.0” x 2.0”
	3-18	20.5” x 10.0” x 3.0”
	3-19	20.5” x 10.0” x 4.0”

FOOTPRINT	MODEL	DIMENSIONS (L x W x H)
Footprint 3	3-20	20.5” x 10.0” x 5.0”
	3-21	20.5” x 10.0” x 6.0”
	3-22	20.5” x 9.5" x 5.0”
	3-23	20.5” x 9.5” x 5.1”
	3-24	20.5” x 9.5” x 5.6”
	3-25	20.5” x 9.5” x 6.1”
	3-26	20.5” x 9.5” x 6.3”
	3-27	20.5” x 9.5” x 6.4”
	3-28	20.5” x 9.5” x 6.6”
	3-29	20.5” x 9.5” x 7.0”
	3-30	20.5” x 9.7” x 2.0”
	3-31	20.5” x 9.7” x 3.8”
	3-32	20.5” x 9.7” x 5.2”
	3-33	20.5” x 9.8” x 2.0”
	3-34	20.5” x 9.8” x 2.1”
	3-35	20.5” x 9.8” x 2.2”
	3-36	20.5” x 9.8” x 2.3”
	3-37	20.5” x 9.8” x 2.5”
	3-38	20.5” x 9.8” x 3.0”
	3-39	20.5” x 9.8” x 3.1”
	3-40	20.5” x 9.8” x 3.3”
	3-41	20.5” x 9.8” x 3.5”
	3-42	20.5” x 9.8” x 3.6”

FOOTPRINT	MODEL	DIMENSIONS (L x W x H)
Footprint 3	3-43	20.5” x 9.8” x 3.7”
	3-44	20.5” x 9.8” x 3.8”
	3-45	20.5” x 9.8” x 3.9”
	3-46	20.5” x 9.8” x 4.0”
	3-47	20.5” x 9.8” x 4.1”
	3-48	20.5” x 9.8” x 4.3”
	3-49	20.5” x 9.8” x 4.4”
	3-50	20.5” x 9.8” x 4.5”
	3-51	20.5” x 9.8” x 4.6”
	3-52	20.5” x 9.8” x 4.7”
	3-53	20.5” x 9.8” x 4.8”
	3-54	20.5” x 9.8” x 5.0”
	3-55	20.5” x 9.8” x 5.3”
	3-56	20.5” x 9.8” x 5.5”
	3-57	20.5” x 9.8” x 5.7”
	3-58	20.5” x 9.8” x 6.0”
	3-59	20.5” x 9.8” x 6.1”
	3-60	20.5” x 9.8” x 6.3”
	3-61	20.5” x 9.8” x 6.6”
	3-62	20.5” x 9.8” x 7.1”
	3-63	20.5” x 9.8” x 7.2”
	3-64	20.6” x 9.7” x 3.4”
	3-65	20.6” x 9.7” x 3.6”
	3-66	20.6” x 9.7” x 4.4”
	3-67	20.6” x 9.7” x 4.7"
	3-68	20.8” x 9.8" x 2.8"
	3-69	20.8” x 9.8” x 5.2”
	3-70	20.9” X 10.0” X 2.3”
	3-71	20.9” x 9.8” x 6.6”
	3-72	21.0” x 10.0” x 4.0”
	3-73	21.0” x 10.0” x 4.2”
	3-74	21.0” x 10.0” x 4.3”
	3-75	21.0” x 10.0” x 6.0”
	3-76	21.0” x 10.1” x 3.1”
	3-77	21.0” x 9.7” x 3.0”
	3-78	21.0” x 9.7” x 3.7”
	3-79	21.0” x 9.7” x 4.2”
	3-80	21.0” x 9.7” x 4.3”
	3-81	21.0” x 9.7” x 4.8”
	3-82	21.0” x 9.7” x 6.2”

FOOTPRINT	MODEL	DIMENSIONS (L x W x H)
Footprint 3	3-83	21.0” x 9.7” x 6.8”
	3-84	21.0” x 9.8” x 2.2”
	3-85	21.0” x 9.8” x 3.5”
	3-86	21.0” x 9.8” x 3.8”
	3-87	21.0” x 9.8” x 4.0”
	3-88	21.0” x 9.8” x 5.6”
	3-89	21.1” x 9.7” x 3.7”
	3-90	21.1” x 9.7” x 6.2”
	3-91	21.1” x 9.7” x 6.4”
	3-92	21.1” x 9.8” x 4.6”
	3-93	21.1” x 9.8” x 6.0”
	3-94	21.2” x 10.0” x 4.5”
	3-95	21.2” x 10” x 5.2”
	3-96	21.2” x 9.7” x 4.8”
	3-97	21.2” x 9.7” x 4.9”
	3-98	21.2” x 9.7” x 5.4”
	3-99	21.3” x 10.0” x 4.9”
	3-100	21.3” x 10.0” x 6.0 ”
	3-101	21.3” x 10.1” x 5.8”
	3-102	21.3” x 8.5” x 5.3”
	3-103	21.4” x 10.0” x 4.5”
	3-104	21.4” x 10.0” x 5.0”
	3-105	21.4” x 10.0” x 6.0”
	3-106	21.4” x 10.1” x 2.9”
	3-107	21.4” x 10.1” x 3.0”
	3-108	21.4” x 10.1” x 3.5”
	3-109	21.4” x 10.1” x 3.7”
	3-110	21.4” x 10.1” x 3.8”
	3-111	21.4” x 10.1” x 4.6”
	3-112	21.4” x 10.1” x 4.7”
	3-113	21.4” x 10.1” x 5.3”
	3-114	21.4” x 10.1” x 6.4”
	3-115	21.4” x 10.1” x 6.8”
	3-116	21.4” x 10.1” x 7.0”
	3-117	21.4” x 9.6” x 5.0”
	3-118	21.4” x 9.6” x 6.0”
	3-119	21.4” x 9.6” x 6.4”
	3-120	21.5” x 10.0” x 3.0"
	3-121	21.5” x 10.0” x 3.8”
	3-122	21.5” x 10.0” x 4.6”

FOOTPRINT	MODEL	DIMENSIONS (L x W x H)
Footprint 3	3-123	21.6” x 9.8” x 4.2”
	3-124	21.6” x 9.9” x 3.0”
	3-125	21.7” x 10.0” x 3.1”
	3-126	21.7” x 9.9” x 4.1”
	3-127	21.7” x 9.9” x 5.0”
	3-128	21.7” x 9.9” x 6.3”
	3-129	21.8” x 10.4” x 4.1”
	3-130	21.8” x 10.5” x 4.7”
	3-131	21.9” x 10.0” x 3.2”
	3-132	21.9” x 10.0” x 3.5”
	3-133	21.9” x 10.0” x 6.0”
	3-134	22.0” x 9.7” x 6.2”
	3-135	22.0” x 10.0” x 6.6”
Footprint 4	4-1	9.0” x 6.5” x 2.5”
	4-2	9.8” x 6.3” x 3.6”
	4-3	9.8” x 8.3” x 2.1”
	4-4	9.8” x 9.0” x 3.5”
	4-6	9.9” x 7.8” x 2.0"

FOOTPRINT	MODEL	DIMENSIONS (L x W x H)
Footprint 5	5-1	10.0” x 10.0” x 2.0”
	5-2	10.0” x 10.0” x 2.3”
	5-3	10.4” x 9.8” x 2.1”
	5-4	10.4” x 9.8” x 2.3”
	5-5	10.4” x 9.8” x 2.5”
	5-6	10.4” x 9.8” x 3.0”
	5-7	10.6” x 10.0” x 3.5”
	5-8	10.6” X 9.7” X 2.9”
	5-9	10.6” X 9.7” X 3.6”
Footprint 6	6-1	12.3” x 8.3” x 2.1”
	6-2	13.3” x 9.3” x 2.1”
	6-3	14.5” x 9.8” x 2.3”
Footprint 7	7-1	15.0” x 10.0” x 2.5”
	7-2	15.8” x 9.8” x 5.2”
	7-3	16.8” x 9.8” x 3.2"
Footprint 8	8-1	15.7” x 4.7” x 2.7”
	8-2	15.8” x 4.5” x 2.5”

F. Technological Characteristics

As was established in this submission, the subject *NuVasive Sterilization Trays* are substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, material composition, sterilization method, and function.

G. Performance Testing

To establish substantial equivalence with a predicate device, the performance testing was conducted to confirm that SAL (10^{-6}) sterility level was achieved at the validated sterilization parameters in prevacuum steam sterilization cycle per ISO 17665-1 and AAMI TIR 12. Upon completion of the SAL (10-6) validations, dry time validation was executed.

H. Conclusions

Based on the indications for use, technological characteristics, performance data, and comparison to predicate device, the subject *NuVasive Sterilization Trays* has been shown to be substantially equivalent to legally marketed predicate device.

Comparison Table for Substantial Equivalence

Characteristics	Predicate Device K102103	Subject Device NuVasive Sterilization Trays
Product Code	KCT	KCT
21 CFR	888.6850	888.6850
System Components	Base, lid, insert trays, brackets, caddies	Base, lid, insert trays, brackets, caddies
Material Composition	Aluminum, Nylon, Silicone, Stainless Steel, Polypropylene, Polyphenylsulfone	Aluminum, Nylon, Silicone, Stainless Steel, Polypropylene, Polyphenylsulfone
Physical Properties	Evenly distributed perforated hole pattern	Evenly distributed perforated hole pattern
Configurations/ Dimensions	Rectangle base with lid, inserts, brackets and caddies; Multiple dimensions to accommodate different product configurations	Rectangle base with lid, inserts, brackets and caddies; Multiple dimensions to accommodate different product configurations
Sterilant Penetration	Sterilant (steam) penetration through perforations in tray	Sterilant (steam) penetration through perforations in tray
Sterilization method	Steam	Steam
Sterilization cycle	Pre-vacuum and Gravity	Pre-vacuum
Exposure temperature	270°F (132°C)	270°F (132°C)
Exposure time	4 minutes	4 minutes
Dry time	20 minutes	30 minutes
Reusable	Yes	Yes

<table>
<tr><th>Characteristics</th><th>Predicate Device
K102103</th><th>Subject Device NuVasive
Sterilization Trays</th></tr>
<tr><td>Indications for Use</td><td>Skeletal Dynamics Sterilization Trays are intended to contain Skeletal Dynamics reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The full DIN and half DIN tray include as accessories an insert to hold instruments and caddy to hold implants and smaller components. The Akro-Vu tray only contains brackets to hold the Akro-Vu System’s reusable components.
The full DIN and half DIN trays are suitable for use in both pre-vacuum steam and high temperature gravity steam serialization methods. The Akro-Vu tray is suitable for use in pre- vacuum steam sterilization method. The trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices.
Validated sterilization parameters for full DIN and half DIN trays and Akro-Vu tray:

<table><tr><td>Method</td><td>Steam
Pre-Vacuum</td><td>High Temp.
Gravity Steam</td></tr><tr><td>Temperature</td><td>270°F</td><td>270°F</td></tr><tr><td>Exposure Time</td><td>4 min</td><td>15 min</td></tr><tr><td>Min Dry Time</td><td>20 min</td><td>20 min</td></tr></table>
Validated sterilization parameters for full DIN and half DIN trays:
<table><tr><td>Method: Steam</td></tr><tr><td>Cycle: High Temperature Gravity Steam</td></tr><tr><td>Temperature: 270°F (132°C)</td></tr><tr><td>Exposure Time: 15 minutes</td></tr><tr><td>Minimum Dry Time: 20 minutes</td></tr></table></td><td>The NuVasive Sterilization Trays are intended to contain NuVasive implants and surgical instruments for sterilization, storage and handling. The NuVasive Sterilization Trays are suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The 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 devices.
Sterilization validations for three level worst case tray (20.5" x 10" x 7.375") included three different loading configurations: implant only content (26.4 lbs.), instrument only content (39.95 lbs.) and mixed instruments and implants content (30.45 lbs.)
Validated worst case loading configurations included 23 instruments with lumens including the following worst case lumen dimensions:
- 0.16 cm x 30.68 cm
- 0.11 cm x 16.64 cm
- 0.72 cm x 33.19 cm
- 0.55 cm x 35.69 cm
Do not exceed a maximum load of 25 lbs in the sterilization tray.
Validated sterilization parameters for NuVasive Sterilization Trays:

<table><tr><td>Method: Steam</td></tr><tr><td>Cycle: Pre-Vacuum</td></tr><tr><td>Temperature: 270°F (132°C)</td></tr><tr><td>Exposure Time: 4 minutes</td></tr><tr><td>Minimum Dry Time: 30 minutes</td></tr><tr><td>Minimum Cool Down Time: 40 minutes</td></tr></table></td></tr>
</table>