July 28, 2022

Misonix Inc.
% John Salerno
Vice President of Regulatory Affairs and Quality Assurance
Misonix
1938 New Highway
Farmingdale, New York 11735

Re: K221235
Trade/Device Name: neXus Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, GEI, LBK
Dated: April 27, 2022
Received: April 29, 2022

Dear John Salerno:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For:
Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221235

Device Name
neXus Ultrasonic Surgical Aspirator System

Indications for Use *(Describe)*
The Misonix Inc. neXus Ultrasonic Surgical Aspirator System is intended for the fragmentation, emulsification and aspiration of both soft and hard (i.e., bone) tissue.
The indications for use for the Standard Handpiece in combination with BoneScalpel and SonicOne OR probe kit accessory configurations, the SonaStar®long and short handpieces in combination with SonaStar probe kit accessory configurations, the BoneScalpel AccessTM handpiece with BoneScalpel AccessTM probe kit accessory configurations, and the SonaStar Elite Handpiece with probe kit accessory configurations are listed below.

Standard Handpiece with BoneScalpel Probe Kits

Indicated for use in the fragmentation, emulsification and aspiration of soft and hard (e.g., bone) tissue in the following surgical specialties:
• Neurosurgery
• Gastrointestinal and Affiliated Organ Surgery
• Urological Surgery
• Plastic and Reconstructive Surgery
• General Surgery
• Orthopedic Surgery
• Gynecology
External genitalia - condyloma - benign tumors (lipomas, fibromas, and leiomyomas) - malignant primary and metastatic tumors of all types and the following cystic lesions: Bartholin's cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts
Abdominal area - any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus except as contraindicated for uterine fibroids.
• Thoracic Surgery
Limited pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and metastatectomies.
• Wound Care
The neXus Ultrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.

Standard Handpiece with SonicOne Probe Kits

Indicated for use in the fragmentation, emulsification and aspiration of soft and hard tissue (i.e. bone) in the following surgical specialty:
• Wound Care
The neXus Ultrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.
• Plastic and Reconstructive Surgery

neXus SonaStar Handpieces with SonaStar Probe Kits

• Indicated for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue in the following surgical specialties:

• Neurosurgery
• Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy
• Urological Surgery - including removal of renal parenchyma during nephrectomy or partial nephrectomy
• Plastic and Reconstructive Surgery
• General Surgery - including removal of benign or malignant tumors or other unwanted tissue in open or minimally invasive general surgical procedures
• Orthopedic Surgery
• Gynecological Surgery – except as contraindicated for uterine fibroids.
• Thoracic Surgery
• Laparoscopic Surgery – including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy
• Thoracoscopic Surgery
The SonaStar Handpieces may also be combined with electrosurgery using optional RF surgery interface components.

Bone Scalpel Access Handpiece with BoneScalpel Access Probe Kits

Indicated for use in the fragmentation and aspiration of soft and hard (e.g.: bone) tissue in the following surgical specialties:
• Neurosurgery
• Gastrointestinal and Affiliated Organ Surgery
• Urological Surgery
• Plastic and Reconstructive Surgery
• General Surgery
• Orthopedic Surgery
• Gynecology
External genitalia - condyloma - benign tumors (lipomas, fibromas, and leiomyomas) - malignant primary and metastatic tumors of all types and the following cystic lesions: Bartholin's cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts
Abdominal area - any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus except as contraindicated for uterine fibroids.
• Thoracic Surgery
Limited pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and metastatectomies.

SonaStar Elite Handpiece with SonaStar Elite Probe Kits

Indicated for use in the fragmentation and aspiration of soft and hard (e.g., bone) tissue in the following surgical specialties:
• Neurosurgery
• Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy
• Urological Surgery - including removal of renal parenchyma during nephrectomy or partial nephrectomy
• Plastic and Reconstructive Surgery
• General Surgery - including removal of benign or malignant tumors or other unwanted tissue in open or minimally invasive general surgical procedures
• Orthopedic Surgery
• Gynecological Surgery – except as contraindicated for uterine fibroids.
• Thoracic Surgery
• Laparoscopic Surgery – including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial

gastrectomy
• Thoracoscopic Surgery
The system may also be combined with electrosurgery using optional RF surgery interface components.

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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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the neXus Ultrasonic Aspirator System is provided below.

1. SUBMITTER

Applicant:	Misonix, a Bioventus Company 1938 New Highway Farmingdale, NY 11735
Contact:	John Salerno Vice President of Regulatory Affairs and Quality Assurance Misonix 1938 New Highway Farmingdale, NY 11735 Main: 631-694-9555 Direct: 631-927-9123 john.salerno@bioventus.com
Submission Correspondent:	Sharon Klugewicz Senior Vice President, Quality and Regulatory Affairs Bioventus 4721 Emperor Blvd. STE 100 Duram, NC 27703 Main: 919-474-6700 Mobile: 516-425-4446 sharon.klugewicz@bioventus.com

Date Prepared: April 26, 2022

DEVICE

Device Trade Name:	neXus Ultrasonic Aspirator System
Device Common Name:	Instrument, Ultrasonic Surgical
Classification Name:	Unclassified
Regulatory Class:	Unclassified
Product Code:	LFL, GEI, LBK

2. PREDICATE DEVICE

Predicate Device:	K200774, CUSA Clarity Ultrasonic Aspirator System, Integra LifeSciences
Reference Devices:	K212960, neXus Ultrasonic Surgical Aspirator System, Misonix Inc. K190160, neXus Ultrasonic Surgical Aspirator System, Misonix Inc.

3. DEVICE DESCRIPTION

The neXus Ultrasonic Surgical Aspirator System is intended for fragmentation, emulsification and aspiration of both soft and hard (i.e., bone) tissue. The system includes a generator housed inside the console. A reusable handpiece is plugged directly into the front panel of the console.

The generator and handpiece are compatible with various single use disposable "probes" which are selected and attached to the handpiece by the end user. An irrigation unit provides sterile irrigant to the operative site. An aspiration system removes the fragmented, emulsified material and waste liquids from the operative site.

Accessories include a wireless footswitch, various probe tip combinations, sterilization trays, probe covers, assembly & disassembly wrenches, irrigation & aspiration tubing sets, and waste collection canisters.

4. INTENDED USE/INDICATIONS FOR USE

The Misonix Inc. neXus® Ultrasonic Surgical Aspirator System is intended for the fragmentation, emulsification and aspiration of both soft and hard (i.e., bone) tissue.

The indications for use for the Standard Handpiece in combination with BoneScalpel® and SonicOne® OR probe kit accessory configurations, the SonaStar® long and short handpieces in combination with SonaStar® probe kit accessory configurations, the BoneScalpel Access™ handpiece with BoneScalpel Access™ probe kit accessory configurations, and the SonaStar Elite Handpiece with probe kit accessory configurations are listed below.

Standard Handpiece with BoneScalpel Probe Kits

Indicated for use in the fragmentation, emulsification and aspiration of soft and hard (e.g., bone) tissue in the following surgical specialties:

- **Neurosurgery**
- **Gastrointestinal and Affiliated Organ Surgery**
- **Urological Surgery**
- **Plastic and Reconstructive Surgery**
- **General Surgery**
- **Orthopedic Surgery**
- **Gynecology**

  External genitalia - condyloma - benign tumors (lipomas, fibromas, and leiomyomas) - malignant primary and metastatic tumors of all types and the following cystic lesions: Bartholin's cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts

  Abdominal area - any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus except as contraindicated for uterine fibroids.

- **Thoracic Surgery**

  Limited pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and metastatectomies.

- **Wound Care**

  The neXus Ultrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.

Standard Handpiece with SonicOne Probe Kits

Indicated for use in the fragmentation, emulsification and aspiration of soft and hard tissue (i.e. bone) in the following surgical specialty:

- **Wound Care**

  The neXus Ultrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.

- **Plastic and Reconstructive Surgery**

neXus SonaStar Handpieces with SonaStar Probe Kits

Indicated for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue in the following surgical specialties:

- **Neurosurgery**
- **Gastrointestinal and Affiliated Organ Surgery** – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy
- **Urological Surgery** - including removal of renal parenchyma during nephrectomy or partial nephrectomy
- **Plastic and Reconstructive Surgery**
- **General Surgery** - including removal of benign or malignant tumors or other unwanted tissue in open or minimally invasive general surgical procedures
- **Orthopedic Surgery**

- **Gynecological Surgery** – except as contraindicated for uterine fibroids.
- **Thoracic Surgery**
- **Laparoscopic Surgery** – including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy
- **Thoracoscopic Surgery**

The SonaStar Handpieces may also be combined with electrosurgery using optional RF surgery interface components.

Bone Scalpel Access Handpiece with BoneScalpel Access Probe Kits

Indicated for use in the fragmentation and aspiration of soft and hard (e.g.: bone) tissue in the following surgical specialties:

- **Neurosurgery**
- **Gastrointestinal and Affiliated Organ Surgery**
- **Urological Surgery**
- **Plastic and Reconstructive Surgery**
- **General Surgery**
- **Orthopedic Surgery**
- **Gynecology**

  External genitalia - condyloma - benign tumors (lipomas, fibromas, and leiomyomas) - malignant primary and metastatic tumors of all types and the following cystic lesions: Bartholin's cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts

  Abdominal area - any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus, or the supporting structures of the uterus except as contraindicated for uterine fibroids.

- **Thoracic Surgery**

  Limited pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and metastatectomies.

SonaStar Elite Handpiece with SonaStar Elite Probe Kits

Indicated for use in the fragmentation and aspiration of soft and hard (e.g., bone) tissue in the following surgical specialties:

- **Neurosurgery**

- **Gastrointestinal and Affiliated Organ Surgery** – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy
- **Urological Surgery** - including removal of renal parenchyma during nephrectomy or partial nephrectomy
- **Plastic and Reconstructive Surgery**
- **General Surgery** - including removal of benign or malignant tumors or other unwanted tissue in open or minimally invasive general surgical procedures
- **Orthopedic Surgery**
- **Gynecological Surgery** – except as contraindicated for uterine fibroids.
- **Thoracic Surgery**
- **Laparoscopic Surgery** – including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy
- **Thoracoscopic Surgery**

The system may also be combined with electrosurgery using optional RF surgery interface components.

5. SUBSTANTIAL EQUIVALENCE

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (K200774, CUSA Clarity).

Device Comparison Table

	Subject Device	**Predicate Device (K200774)**
510(k) Number	TBD	K200774
Company	Misonix, a Bioventus company	Integra LifeSciences
Device Name	neXus Ultrasonic Surgical Aspirator System	CUSA Clarity Ultrasonic Surgical Aspirator System
Product Code	LFL Subsequent product code: GEI	LFL Subsequent product code: LBK

	Subject Device	Predicate Device (K200774)
Compatible Handpieces	SonaStar Elite (SSE) Handpiece (36 kHz) [Part number 100-26-0001] neXus® Standard Handpiece (23 kHz) [Part number: 100-21-0001] neXus® SonaStar® Short Handpiece (23 kHz) [Part number 100-24-0001] neXus® SonaStar® Long Handpiece (23 kHz) [Part number 100-25-0001] neXus® BoneScalpel Access™ Handpiece (23 kHz) [Part number 100-22-0001]	CUSA Clarity 36 kHz Handpiece [Part number C7036] CUSA Clarity 23kHz Handpiece [Part number C7023]
Principle of Operation	Handpiece-probe assembly vibrate at resonant frequency resulting from the conversion of the electrical drive signal from the neXus console into mechanical vibrations by the piezo stack.	Handpiece-probe assembly vibrate at resonant frequency resulting from the conversion of the electrical drive signal from the CUSA Clarity console into mechanical vibrations by the piezo stack.
Reusable Accessories	neXus Console neXus Cart neXus Aspiration Filter neXus Footswitch neXus Power Cords neXus SonaStar Elite 36 kHz Handpiece neXus Handpiece Front Housing neXus SonaStar Elite 36 kHz Handpiece Torque Wrench. neXus SonaStar Elite 36 kHz Handpiece Counter Wrenches neXus Handpiece Cleaning Brush Kits neXus SonaStar Sterilization Trays	CUSA Clarity Console CUSA Clarity Cart CUSA Clarity Contamination Guard CUSA Clarity Footswitch CUSA Clarity Power Cords CUSA Clarity 36 kHz Handpiece CUSA Clarity 36 kHz Handpiece Torque Wrenches CUSA Clarity 36 kHz Handpiece Torque Base CUSA Clarity 36 kHz Cleaning Brushes CUSA Clarity 36 kHz Sterilization Trays
Disposable Accessories	neXus Hard Plastic Sheaths neXus Soft Rubber Sheaths Tip Stylets Aspiration Canister Single Use Probe and Tubeset Kits	CUSA Clarity Nosecone CUSA Clarity Flue Tip Stylets Aspiration Canister Specimen Canister Single Use Probe Tips Single Use Aspiration Tubing Single Use Irrigation Tubing

	Subject Device	Predicate Device (K200774)
Cleaning & Sterilization	Reusable accessories are to be cleaned and sterilized by moist heat (steam) by the user prior to use using cleaning and sterilization protocols published in the IFU. Single use items are provided sterile and are to be disposed of after use.	Reusable accessories are to be cleaned and sterilized by moist heat (steam) by the user prior to use using cleaning and sterilization protocols published in the IFU. Single use items are provided sterile and are to be disposed of after use.
Probe and Tubeset Kits	Probe and Tubeset Kits are provided. Tubesets are bi-lumen designs with an irrigation and aspiration tube leg.	Separate probe, irrigation tubeset, and aspiration tubeset packages are provided.
Electrosurgery	The subject SonaStar Elite 36 kHz handpiece system can interface with electrosurgery generators for monopolar electro cautery using an optional RF surgery interface component.	The CUSA Clarity 36 kHz handpiece system does not interface with electrosurgery generators and does not offer an optional RF surgery interface component.
Console		
Generator Classification Applied Part Classification	Class 1 Type BF Applied Part	Class 1 Type CF Applied Part
Power Input Voltage	100-240 VAC	100-240V VAC
Power Input Current	5A max	5A max
Power Input Frequency	50/60Hz	50/60Hz
Functions	Vibration Irrigation Aspiration	Vibration Irrigation Aspiration
Vibration System	Frequency: 34.5-37.0 kHz Amplitude: Up to 206 microns	Frequency: 35.55 - 36.25 kHz Amplitude: Up to 210 microns
Irrigation pump	Peristaltic pump	Peristaltic pump
Irrigation Flow Rate	Normal: 2-20ml/min Flush: 25ml/min	Normal: 2-20ml/min Flush: 25ml/min
Aspiration Vacuum Pump	Built-in vacuum pump	Built-in vacuum pump
Aspiration Vacuum Specification	Max: 635 mm (25.0 in) mercury	Max: 640 mm (25.2 in) mercury

	Subject Device	**Predicate Device (K200774)**
Footswitch	Wireless Optional Wired Pedal and Push button PRESET: Operation at set Ultrasound, Irrigation and Aspiration regardless of Pedal position during actuation LINEAR: Amplitude control with the degree of pedal depression FLUSH: Actuated via Push Button switch	- Wired Dual Pedal STANDARD: Operation at set Ultrasound, Irrigation and Aspiration regardless of Pedal position during actuation PROPORTIONAL: Amplitude control with the degree of pedal depression FLUSH: Actuated via Pedal
Console Display	Touch screen graphical user interface	Touch screen graphical user interface
Console GUI	Default Settings: Vibration: 60% Irrigation: 25% Aspiration: 60% Footswitch mode: Preset Aspiration mode: Lap Endo Mode Off User Settings: Vibration: Incremental adjustment = 5 Range = 5 to 100% Irrigation: Incremental adjustment = 5 Range = 5 to 100% Aspiration: Incremental adjustment = 5 Range = 5 to 100%	Default Settings: Vibration: 60% Irrigation: 3 ml/min Aspiration: 60% Footswitch mode: Standard Aspiration mode: Constant Tissue Select: Off User Settings: Vibration: Incremental adjustment = 5 Range = 10 to 100% Irrigation: Incremental adjustment = 1 Range = 2 to 20ml/min Aspiration: Incremental adjustment = 5 Range = 10 to 100%
Console dimensions	11.5” H x 16” W x 17” D| (*) 292mm H x406 mm W x 432mmD (*) Dimensions, without cart	19.5” H x 13.75” W x 18” D (*) 493mm H x349 mm W x 457mm D (*) Dimensions, without cart
Console weight without cart	45 lbs. | 20.4 kg	65 lbs. | 29.5 kg
Cart	Cart provides a secure platform for the console. It has a handle and locking casters and provides storage for the footswitch and power cord.	Cart provides a secure platform for the console. It has a handle and locking casters and provides storage for the footswitch and power cord.

6. PERFORAMNCE DATA

Biocompatibility Testing

The ultrasonic tip (and sheath, when applicable) are direct patient contacting devices classified as externally communicating devices, in contact with tissue and/or bone, with limited contact duration (≤ 24h) based on their intended use. The irrigation tubing, which is in contact with the fluid path, is an indirect patient contacting device classified as externally communicating devices, in contact with tissue and/or bone, with limited contact (≤ 24h).

The subject device was compared to the biocompatibility master products for the original premarket clearance (K190160) for the neXus Ultrasonic Surgical Aspirator System and for the Misonix BoneScalpel Access Handpiece and Probe and Tubeset Kits (K212060).

Like the master products, the subject device accessories are categorized as an externally communicating, tissue/bone contact, limited duration device. The biocompatibility endpoints for this class of device are:

- Cytotoxicity: ISO 10993-5
- Sensitization: ISO 10993-10
- Irritation or Intracutaneous Reactivity: ISO 10993-10
- Acute Systemic Toxicity: ISO 10993-11
- Pyrogenicity: USP <151>

The change in the indications for use for the subject device comparted to the master products do not raise new questions of safety related to biocompatibility. There is no change in target populations, target anatomical sites, use environment, user population, category of body contact, body tissue contact, duration of contact, biocompatibility endpoints, type of contact (direct, indirect, or transient).

There is no change in principle of operation, geometry, sterilization process, or manufacturing process between the subject product and the master products that would raise new questions about biocompatibility. There is one new material, two minor changes in material formulation, and changes in manufacturers. Biocompatibility testing was required based on the material changes for the subject product.

The new materials were assembled in a master product configuration and submitted for biocompatibility testing to the endpoints listed above. The results meet the requirements of ISO 10993-1.

Sterilization and Shelf Life

Sterility

Single Use Disposable Components – provided Sterile

The single The Probe Kits are provided sterile and are for single use. Each contains the following basic components:

- Probe Tip assembly: titanium horn + tip, available in various sizes and types, some are provided with additional fittings, O-rings, stylets, etc.
- Probe Sheath: rigid plastic or silicone
- Tubing Set: irrigation only or irrigation + aspiration, and tubing "pucks"

These disposable components are supplied in a combined, sterile package, based on the probe tip selected by the customer.

Reusable Components – End User Cleaned and Sterilized

All reusable handpiece parts and accessories are end user cleaned and sterilized before each use as per the validated instructions contained in the Instructions for Use of each Handpiece. The instructions for use also provide the validated expected use life for the reusable components.

Shelf Life

The single use disposable kits have now been tested to support a 37-month shelf life. The results of the accelerated aged testing performed on EtO sterilized test articles and packaging materials demonstrated that the test articles and associated sterile barrier and outer packaging are found to be acceptable for use with a 37-month shelf life.

The single use disposable kits have also been tested to support a 13-month ambient conditions real time shelf life.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety was conducted on the subject device in accordance with the following standards:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012
- IEC 60601-2-2: 2017
- IEC 60601-1-2:2015

There have been no device modifications related to the wireless communications between the footswitch and the console, therefore the wireless coexistence testing submitted under K190160 remains valid.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Bench Testing

The following tests were performed to support the claim of substantial equivalence:

- Acoustic Intensity Testing

- Applied Part Temperature Testing – Normal and Abnormal Operating Conditions
- Probe Vibration Testing
- Soft Tissue Performance Testing
- Probe Life Testing

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

7. CONCLUSION

The substantial equivalence information provided in this submission demonstrates that the subject device is substantially equivalent to the predicate device in both indications for use and technological characteristics. Therefore, the subject device can be found substantially equivalent to the predicate device.