July 30, 2026

Misonix, LLC
Shreyash Jalgaonkar
Principal Regulatory Affairs Specialist
1938 New Hwy.
Farmingdale, New York 11735

Re: K261448
Trade/Device Name: neXus Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, GEI
Dated: April 30, 2026
Received: May 1, 2026

Dear Shreyash Jalgaonkar:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.07.30 18:39:32 -04'00'

Colin K. Chen, Ph.D.
Acting 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261448 ?

Please provide the device trade name(s). ?

neXus Ultrasonic Surgical Aspirator System

Please provide your Indications for Use below. ?

The Misonix LLC. 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 Kit
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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(k) Summary

1. SUBMITTER

Submitter:	Misonix LLC 1938 New Highway Farmingdale, NY 11735
Contact Information – Primary:	Shreyash Jalgaonkar Principal Regulatory Affairs Specialist 4721 Emperor Boulevard Suite 100 Durham, NC 27703, U.S.A Contact Number: (617) 820-6862 Email: Shreyash.Jalgaonkar@Bioventus.com
Contact Information – Alternate:	William Heard Director, Regulatory Affairs 4721 Emperor Boulevard Suite 100 Durham, NC 27703, U.S.A Contact Number: (919) 539-7245 Email: William.Heard@Bioventus.com
Trade Name:	neXus Ultrasonic Surgical Aspirator System
Classification:	**Product Code:** LFL **Name:** Instrument, Ultrasonic Surgical **Device Class:** Unclassified **Secondary Product Code:** GEI **Name:** Electrosurgical, Cutting & Coagulation & Accessories **Regulation Number:** 878.4400 **Device Class:** 2 **Classification Panel:** General and Plastic Surgery
Establishment Registration	2435119
Reason for Submission	To align the neXus Ultrasonic Surgical Aspirator System with current regulatory expectations.

Type of Submission	Traditional 510(k)
Date Prepared	July 28, 2026

2. PREDICATE DEVICE

Predicate Device: neXus Ultrasonic Surgical Aspirator System (K231117)

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 system 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, disposable electrocautery cable, and waste collection canisters.

4. INDICATIONS FOR USE

Indications for Use Statement:
The Misonix LLC. 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.

BoneScalpel 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

The table below compares the key technological features of the subject device to the predicate device (K23117).

Table 1: Technological Comparison

	Predicate Device (K231117)	**Subject Device**
510(k) Number	K231117	TBD
Company	Misonix, a Bioventus company	Misonix LLC
Device Name	neXus Ultrasonic Surgical Aspirator System	neXus Ultrasonic Surgical Aspirator System
Product Code	LFL Subsequent product code: GEI	LFL Subsequent product code: GEI
Indications for Use	See Section 1	See Section 1
Handpieces	neXus® Standard Handpiece [100-21-0001] neXus® SonaStar® Short Handpiece [100-24-0001] neXus® SonaStar® Long Handpiece [100-25-0001] neXus® BoneScalpel Access™ Handpiece [100-22-0001] SonaStar® Elite (SSE) Handpiece [100-26-0001]	neXus® Standard Handpiece [100-21-0001] neXus® SonaStar® Short Handpiece [100-24-0001] neXus® SonaStar® Long Handpiece [100-25-0001] neXus® BoneScalpel Access™ Handpiece [100-22-0001] SonaStar® Elite (SSE) Handpiece [100-26-0001]
Principle of Operation	Handpiece-probe assembly vibrates 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 vibrates at resonant frequency resulting from the conversion of the electrical drive signal from the neXus console into mechanical vibrations by the piezo stack.
Materials of Construction	Front Driver: Titanium alloy	Front Driver: Titanium alloy
	Piezo ceramics: PZT (lead zirconate titanate)	Piezo ceramics: PZT (lead zirconate titanate)
	Housing: PPSU	Housing: PPSU
	Cable: Electrical conductors, electrical shield, silicone jacket	Cable: Electrical conductors, electrical shield, silicone jacket
Reusable Accessories	100-60-0000	100-60-0000

	Predicate Device (K231117)	Subject Device
	Standard Handpiece Counter Wrench 100-61-0000 Standard Handpiece Torque Wrench 100-62-0000 SonaStar Handpiece Counter Wrench 100-63-0000 Handpiece Torque Wrench 100-64-0000 Access Elite Counter Wrench 100-70-0000 Standard Sterilization Tray 100-71-0000 SonaStar Sterilization Tray	Standard Handpiece Counter Wrench 100-61-0000 Standard Handpiece Torque Wrench 100-62-0000 SonaStar Handpiece Counter Wrench 100-63-0000 Handpiece Torque Wrench 100-64-0000 Access Elite Counter Wrench 100-70-0000 Standard Sterilization Tray 100-71-0000 SonaStar Sterilization Tray
	100-72-0000 BoneScalpel Access Sterilization Tray 100-73-0000 SonaStar Elite Sterilization Tray 100-21-0002 Standard Front Housing (BoneScalpel) 100-21-0003 Standard Front Housing (SonicOne) 100-24-0002 SonaStar Long Housing (Short) 100-24-0003 SonaStar Short Housing (Short)	100-72-0000 BoneScalpel Access Sterilization Tray 100-73-0000 SonaStar Elite Sterilization Tray 100-21-0002 Standard Front Housing (BoneScalpel) 100-21-0003 Standard Front Housing (SonicOne) 100-24-0002 SonaStar Long Housing (Short) 100-24-0003 SonaStar Short Housing (Short)

	Predicate Device (K231117)	**Subject Device**
	100-24-0004 SonaStar Lap Housing (Short) 100-25-0002 SonaStar Mid Housing (Long) 100-25-0003 SonaStar Front Housing (Long) 100-25-0002 SonaStar Mid Housing (Long)	100-24-0004 SonaStar Lap Housing (Short) 100-25-0002 SonaStar Mid Housing (Long) 100-25-0003 SonaStar Front Housing (Long) 100-25-0002 SonaStar Mid Housing (Long)
	100-26-0003 SonaStar Elite Front Housing Smooth	100-26-0003 SonaStar Elite Front Housing Smooth
Reprocessing (Cleaning & Sterilization or Reusable Accessories)	Cleaning and Sterilize as per 100-21-1000 Standard Handpiece IFU Clean and Sterilize as per 100-22-1000 BoneScalpel Access Handpiece IFU Clean and Sterilize as per 100-24-1000 SonaStar Handpiece IFU Clean and Sterilize as per 100-26-1000 SonaStar Elite Handpiece IFU	Cleaning and Sterilize as per 100-21-1000 Standard Handpiece IFU Clean and Sterilize as per 100-22-1000 BoneScalpel Access Handpiece IFU Clean and Sterilize as per 100-24-1000 SonaStar Handpiece IFU Clean and Sterilize as per 100-26-1000 SonaStar Elite Handpiece IFU
Probes cleared in K190160	110-31-1110 BoneScalpel 10mm, Blunt Blade	110-31-1110 BoneScalpel 10mm, Blunt Blade
	110-31-1120 BoneScalpel 20mm, Blunt Blade	110-31-1120 BoneScalpel 20mm, Blunt Blade
	110-31-1125 BoneScalpel 25mm, Blunt Blade	110-31-1125 BoneScalpel 25mm, Blunt Blade

	Predicate Device (K231117)	**Subject Device**
	110-31-1121 BoneScalpel 20mm, Uni-lateral Serrated Blade	110-31-1121 BoneScalpel 20mm, Uni-lateral Serrated Blade
	110-31-2110 BoneScalpel 10mm MIS, Blunt Blade	110-31-2110 BoneScalpel 10mm MIS, Blunt Blade
	110-31-2120 BoneScalpel 20mm MIS, Blunt Blade	110-31-2120 BoneScalpel 20mm MIS, Blunt Blade
	150-32-2120: BoneScalpel Access MIS 20mm Blade & Tubeset	150-32-2120: BoneScalpel Access MIS 20mm Blade & Tubeset
	110-31-1210 BoneScalpel Micro Hook Shaver	110-31-1210 BoneScalpel Micro Hook Shaver
	110-31-1220 BoneScalpel Macro Hook Shaver	110-31-1220 BoneScalpel Macro Hook Shaver
	110-31-1230 BoneScalpel Diamond Shaver	110-31-1230 BoneScalpel Diamond Shaver
	110-31-2210 BoneScalpel Micro Hook MIS Shaver	110-31-2210 BoneScalpel Micro Hook MIS Shaver
	110-31-5501 Standard Decompression Kit (20mm Blade, microhook shaver & tubeset)	110-31-5501 Standard Decompression Kit (20mm Blade, microhook shaver & tubeset)
	130-35-1411 SonaStar 1.1 mm Precision Short Tip & Tubeset	130-35-1411 SonaStar 1.1 mm Precision Short Tip & Tubeset
	130-35-1416 SonaStar 1.6 mm Micro Short Tip & Tubeset	130-35-1416 SonaStar 1.6 mm Micro Short Tip & Tubeset

	Predicate Device (K231117)	**Subject Device**
	130-35-1419 SonaStar 1.9 mm Standard Short Tip and Tubeset	130-35-1419 SonaStar 1.9 mm Standard Short Tip and Tubeset
	130-33-2411 SonaStar 1.1 mm Precision Long Curved Tip & Tubeset	130-33-2411 SonaStar 1.1 mm Precision Long Curved Tip & Tubeset
	130-33-2416 SonaStar 1.6 mm Micro Long Curved Tip & Tubeset	130-33-2416 SonaStar 1.6 mm Micro Long Curved Tip & Tubeset
	130-33-2419 SonaStar 1.9 mm Standard Long Curved Tip & Tubeset	130-33-2419 SonaStar 1.9 mm Standard Long Curved Tip & Tubeset
	130-35-1499 SonaStar 1.9 mm Standard Short Tip & Tubeset	130-35-1499 SonaStar 1.9 mm Standard Short Tip & Tubeset
	130-33-3419 SonaStar Deep Access, 1.9 mm Standard Long Tip & Tubeset	130-33-3419 SonaStar Deep Access, 1.9 mm Standard Long Tip & Tubeset
	130-35-1220 SonaStar Cylindrical Shaver Short Tip with Aspiration & Tubeset	130-35-1220 SonaStar Cylindrical Shaver Short Tip with Aspiration & Tubeset
	130-33-2210 Micro Hook Shaver Long Tip with Aspiration and Tubeset	130-33-2210 Micro Hook Shaver Long Tip with Aspiration and Tubeset
	120-31-10X1 SonicOne Hatched Probe & Tubeset	120-31-10X1 SonicOne Hatched Probe & Tubeset
	120-31-13X2 SonicOne SonicVac & Tubeset	120-31-13X2 SonicOne SonicVac & Tubeset
	12931-13C2 SonicOne SharpVac & Tubeset	12931-13C2 SonicOne SharpVac & Tubeset

	Predicate Device (K231117)	**Subject Device**
	120-31-10R1 SonicOne Cylindrical Probe & Tubeset	120-31-10R1 SonicOne Cylindrical Probe & Tubeset
Probes cleared in K212060	150-32-2120: BoneScalpel Access MIS 20mm Blade & Tubeset	150-32-2120: BoneScalpel Access MIS 20mm Blade & Tubeset
	150-32-2210: BoneScalpel Access MIS Micro Hook Shaver & Tubeset	150-32-2210: BoneScalpel Access MIS Micro Hook Shaver & Tubeset
	150-32-5501: BSA MIS Decompression (Blade+Shaver) Kit & Tubeset	150-32-5501: BSA MIS Decompression (Blade+Shaver) Kit & Tubeset
	130-35-5502 SonaStar Shaver, Aspirator & Tubeset Kit	130-35-5502 SonaStar Shaver, Aspirator & Tubeset Kit
	120-31-13C3 SonicOne Curette Tip Excel Kit	120-31-13C3 SonicOne Curette Tip Excel Kit
Probes cleared in K221235	130-26-2416 SonaStar Elite 1.6mm Micro Long Tip & Tubeset	130-26-2416 SonaStar Elite 1.6mm Micro Long Tip & Tubeset
	130-26-2498 SonaStar Elite 1.6mm Notched Long Tip & Tubeset	130-26-2498 SonaStar Elite 1.6mm Notched Long Tip & Tubeset
	130-26-2419 SSE 1.9mm Standard Long Tip & Tubeset	130-26-2419 SSE 1.9mm Standard Long Tip & Tubeset
	130-26-2499 SonaStar Elite 1.9mm Notched Long Tip & Tubeset	130-26-2499 SonaStar Elite 1.9mm Notched Long Tip & Tubeset
Cleaning and Sterilization of Sterile Single Use Devices	EtO Sterilization Identical Sterilization Cycles	EtO Sterilization Identical Sterilization Cycles

	Predicate Device (K231117)	**Subject Device**
Shelf-Life Sterile Single Use Devices	3 Years Identical Sterile Barrier Packaging	3 Years Identical Sterile Barrier Packaging
Electrosurgery Accessory	100-29-0000 SonaStar Monopolar Handswitch Cable	100-29-0000 SonaStar Monopolar Handswitch Cable
P/N	100-10-0000 neXus Console	100-10-0000 neXus Console
Classification	Class 1 Type BF Applied Part	Class 1 Type BF Applied Part
Power Input Voltage	100-240 VAC	100-240 VAC
Power Input Current	5 A max	5 A max
Power Input Frequenc y	50/60Hz	50/60Hz
Ground Leakage	500 µA (max.)	500 µA (max.)
Functions	Vibration Irrigation Aspiration	Vibration Irrigation Aspiration
Vibration System	Continuous Wave Pulsed Wave Frequency: 22.0-24.5 kHz / Amplitude: up to 355 microns 34.5-37.0 kHz / Amplitude: up to 206 microns	Continuous Wave Pulsed Wave Frequency: 22.0-24.5 kHz / Amplitude: up to 355 microns 34.5-37.0 kHz / Amplitude: up to 206 microns
Irrigation pump	Peristaltic pump	Peristaltic pump

	Predicate Device (K231117)	**Subject Device**
Irrigation Flow Rate	Standard Handpiece Min: 12-18 ml/min – Max: 67-85 ml/min Flush: 67-85 ml/min SonaStar Long and Short Handpieces Min: 1-3 ml/min – Max: 9-14 ml/min Flush: 25-29ml/min Bone Scalpel Access Handpiece Min: 1-3 ml/min – Max: 67-85 ml/min Flush: 67-85 ml/min SonaStar Elite Handpiece Min: 1-3 ml/min – Max: 17-23 ml/min Flush: 25-29ml/min	Standard Handpiece Min: 12-18 ml/min – Max: 67-85 ml/min Flush: 67-85 ml/min SonaStar Long and Short Handpieces Min: 1-3 ml/min – Max: 9-14 ml/min Flush: 25-29ml/min Bone Scalpel Access Handpiece Min: 1-3 ml/min – Max: 67-85 ml/min Flush: 67-85 ml/min SonaStar Elite Handpiece Min: 1-3 ml/min – Max: 17-23 ml/min Flush: 25-29ml/min
Vacuum Pump	Dual Vacuum Head Pump, 24V	Dual Vacuum Head Pump, 24V
Vacuum Specification	Min: 2.0 inHg or lower Max: 25 inHg Vacuum Sleep Mode: 0 inHg	Min: 2.0 inHg or lower Max: 25 inHg Vacuum Sleep Mode: 0 inHg
Footswitch	100-50-0000 neXus Wireless Footpedal 100-51-0000 neXus Wired Footpedal	100-50-0000 neXus Wireless Footpedal 100-51-0000 neXus Wired Footpedal
Console Display	neXus Console with touch screen graphical user interface	neXus Console with touch screen graphical user interface

	Predicate Device (K231117)	Subject Device
Console GUI	Standard Handpiece DEFAULT SETTINGS Vibration: 70 Irrigation: 70 Aspiration: Disabled Lap Endo Mode: Disabled 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% SonaStar Handpieces DEFAULT SETTINGS Vibration: 50 Irrigation: 50 Aspiration: 50 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% BoneScalpel Access Handpiece DEFAULT SETTINGS Vibration: 70	Standard Handpiece DEFAULT SETTINGS Vibration: 70 Irrigation: 70 Aspiration: Disabled Lap Endo Mode: Disabled 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% SonaStar Handpieces DEFAULT SETTINGS Vibration: 50 Irrigation: 50 Aspiration: 50 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% BoneScalpel Access Handpiece DEFAULT SETTINGS Vibration: 70

	Predicate Device (K231117)	Subject Device
	Irrigation: 70 Aspiration: 50 Lap Endo Mode: On USER SETTINGS Vibration: Incremental adjustment = 5 Range = 5 to 100% Irrigation: Incremental adjustment = 1 Range = 1 to 20% Incremental adjustment = 5 Range = 20 to 100% Aspiration: Incremental adjustment = 5 Range = 5 to 100% SonaStar Elite Handpiece DEFAULT SETTINGS Vibration: 60 Irrigation: 25 Aspiration: 60 Lap Endo Mode: Off DTC (DYNAMIC TISSUE RESPONSE): 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%	Irrigation: 70 Aspiration: 50 Lap Endo Mode: On USER SETTINGS Vibration: Incremental adjustment = 5 Range = 5 to 100% Irrigation: Incremental adjustment = 1 Range = 1 to 20% Incremental adjustment = 5 Range = 20 to 100% Aspiration: Incremental adjustment = 5 Range = 5 to 100% SonaStar Elite Handpiece DEFAULT SETTINGS Vibration: 60 Irrigation: 25 Aspiration: 60 Lap Endo Mode: Off DTC (DYNAMIC TISSUE RESPONSE): 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%

	Predicate Device (K231117)	**Subject Device**
	DTC (DYNAMIC TISSUE RESPONSE): Incremental adjustment = 1 Range = 1 to 6	DTC (DYNAMIC TISSUE RESPONSE): Incremental adjustment = 1 Range = 1 to 6
Console Software	v1.10 RC0	v1.11 RC0
Dimensions wo/Cart	11.5” H x 16” W x 17” D 292mm H x406 mm W x 432mm D	11.5” H x 16” W x 17” D 292mm H x406 mm W x 432mm D
Weight wo/Cart	45 lbs. | 20.4 kg	45 lbs. | 20.4 kg

6. PERFORMANCE DATA

Biocompatibility Data

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).

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>

There have been no modifications related to patient contacting materials, therefore the biocompatibility testing submitted under K221235 remains valid.

Sterilization and Shelf Life

Sterility

Single Use Disposable Components – provided Sterile
The single The Probe Kits are provided with 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 were tested to support a 37-month shelf life. The results of the accelerated aged testing along with real-time aging 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 study concluded that the device maintains sterility and performance through the labeled 37-month expiration period.

Electrical Safety and Electromagnetc compatibility

No changes have been made to the device that would impact its electromagnetic compatibility since clearance under K231117. The testing was performed according to the recognized edition of IEC 60601-1-2 on the subject device.

The neXus Console with compatible handpieces was tested in accordance with IEC 60601-1:2005 (3rd Edition) + A1:2012 + A2:2020 (Edition 3.2), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, with the exception of Clause 11.7 regarding biocompatibility, which is addressed separately. The device passed all applicable tests, including U.S. national deviations.

Electrical, mechanical, and thermal safety testing included evaluation of electrical shock protection, insulation, grounding, leakage currents, dielectric strength, mechanical strength, stability, and protection against excessive temperatures under normal and single-fault conditions. The testing demonstrated compliance with the requirements for basic safety and essential performance.

In addition, relevant sections of IEC 60601-2-2, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high-frequency surgical equipment and high-frequency surgical accessories, were evaluated, as applicable, to verify that active accessory insulation and associated safety requirements were met.

Software Verification and Validation Testing

Software verification and validation testing was conducted and a summary of testing provided. The software classification for this device is unchanged as a major level of concern. The following verification tests were conducted:

- DTC DSP pulse mode verification
- DTC GUI verification
- Fault detection and response test using the SonaStar Elite handpiece
- neXus test and calibration (Regression testing)
- System performance verification (Regression testing)
- SonaStar Elite GUI verification (Regression testing)

Bench Testing

The following bench testing was conducted to support the claim of substantial equivalence:

- Functional testing
- Simulated use testing
- Comparative durability 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.

CONCLUSION

Technological comparison and comparative performance testing demonstrated sufficient similarity of the subject device to the predicate. Therefore, the subject device was found to be substantially equivalent in terms of safety and effectiveness to the predicate device for requested indications for use.