June 23, 2023

Misonix, LLC, a Bioventus Company
John Salerno
Vice President of Regulatory Affairs and Quality Assurance
1938 New Highway
Farmingdale, New York 11735

Re: K231117
Trade/Device Name: neXus Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, GEI
Dated: May 26, 2023
Received: May 26, 2023

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.23 07:57:22 -04'00'

Mark Trumbore, 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)*
K231117

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 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.

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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1. SUBMITTER

Applicant:

Misonix

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:

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

Date Prepared: June 22, 2023

2. DEVICE

Device Trade Name:	neXus Ultrasonic Surgical Aspirator System
Device Common Name:	Instrument, ultrasonic surgical
Review Panel:	General and Plastic Surgery
Classification Name	Unclassified
Regulatory Class:	Unclassified

Product Code: LFL, GEI

3. PREDICATE DEVICE

Predicate Device: neXus Ultrasonic Aspirator System with SonaStar Elite Handpiece (K221235)

The predicate device has not been subject to a design-related recall.

4. 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.

5. INDICATIONS FOR USE

Indications for Use Statement:

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.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The indications for use are identical.

Technological Comparisons

The table below compares the key technological features of the subject devices to the predicate device (K221235, Misonix, a Bioventus Company, neXus Ultrasonic Aspirator System with SonaStar Elite Handpiece).

Table 1: Technological Comparison

	Predicate Device (K221235)	**Subject Device**
510(k) Number	K221235	TBD
Company	Misonix, a Bioventus company	Misonix, a Bioventus company
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 5	See Section 5
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]	Identical Identical Identical Identical Identical
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.	Identical
Materials of Construction	Front Driver: Titanium alloy	Identical
	Piezo ceramics: PZT (lead zirconate titanate)	Identical
	Housing: PPSU	Identical
	Cable: Electrical conductors, electrical shield, silicone jacket	Identical
Reusable Accessories	100-60-0000 Standard Handpiece Counter Wrench 100-61-0000 Standard Handpiece Torque Wrench 100-62-0000 SonaStar Handpiece Counter Wrench 100-63-0000 Handpiece Torque Wrench	Identical Identical Identical Identical

	Predicate Device (K221235)	Subject Device
	100-64-0000 Access Elite Counter Wrench	Identical
	100-70-0000 Standard Sterilization Tray	Identical
	100-71-0000 SonaStar Sterilization Tray	Identical
	100-72-0000 BoneScalpel Access Sterilization Tray	Identical
	100-73-0000 SonaStar Elite Sterilization Tray	Identical
	100-21-0002 Standard Front Housing (BoneScalpel)	Identical
	100-21-0003 Standard Front Housing (SonicOne)	Identical
	100-24-0002 SonaStar Long Housing (Short)	Identical
	100-24-0003 SonaStar Short Housing (Short)	Identical
	100-24-0004 SonaStar Lap Housing (Short)	Identical
	100-25-0002 SonaStar Mid Housing (Long)	Identical
	100-25-0003 SonaStar Front Housing (Long)	Identical
	100-25-0002 SonaStar Mid Housing (Long)	Identical
	100-26-0003 SonaStar Elite Front Housing Smooth	

	Predicate Device (K221235)	Subject Device
Reprocessing (Cleaning & Sterilization or Reusable Accessories)	Cleaning and Sterilize as per 100-21-1000 Standard Handpiece IFU	Identical
	Clean and Sterilize as per 100-22-1000 BoneScalpel Access Handpiece IFU	Identical
	Clean and Sterilize as per 100-24-1000 SonaStar Handpiece IFU	Identical
	Clean and Sterilize as per 100-26-1000 SonaStar Elite Handpiece IFU	Identical
Probes & Probe Tips		
Probes cleared in K190160	110-31-1110 BoneScalpel 10mm, Blunt Blade	Identical
	110-31-1120 BoneScalpel 20mm, Blunt Blade	Identical
	110-31-1125 BoneScalpel 25mm, Blunt Blade	Identical
	110-31-1121 BoneScalpel 20mm, Uni-lateral Serrated Blade	Identical
	110-31-2110 BoneScalpel 10mm MIS, Blunt Blade	Identical
	110-31-2120 BoneScalpel 20mm MIS, Blunt Blade	Identical
	150-32-2120: BoneScalpel Access MIS 20mm Blade & Tubeset	Identical
	110-31-1210 BoneScalpel Micro Hook Shaver	Identical
	110-31-1220 BoneScalpel Macro Hook Shaver	Identical
	110-31-1230 BoneScalpel Diamond Shaver	Identical
	110-31-2210 BoneScalpel Micro Hook MIS Shaver	Identical
	110-31-5501 Standard Decompression Kit (20mm Blade, microhook shaver & tubeset)	Identical
	130-35-1411 SonaStar 1.1 mm Precision Short Tip & Tubeset	Identical

	Predicate Device (K221235)	**Subject Device**
	130-35-1416 SonaStar 1.6 mm Micro Short Tip & Tubeset	Identical
	130-35-1419 SonaStar 1.9 mm Standard Short Tip and Tubeset	Identical
	130-33-2411 SonaStar 1.1 mm Precision Long Curved Tip & Tubeset	Identical
	130-33-2416 SonaStar 1.6 mm Micro Long Curved Tip & Tubeset	Identical
	130-33-2419 SonaStar 1.9 mm Standard Long Curved Tip & Tubeset	Identical
	130-35-1499 SonaStar 1.9 mm Standard Short Tip & Tubeset	Identical
	130-33-3419 SonaStar Deep Access, 1.9 mm Standard Long Tip & Tubeset	Identical
	130-35-1220 SonaStar Cylindrical Shaver Short Tip with Aspiration & Tubeset	Identical
	130-33-2210 Micro Hook Shaver Long Tip with Aspiration and Tubeset	Identical
	120-31-10X1 SonicOne Hatched Probe & Tubeset	Identical
	120-31-13X2 SonicOne SonicVac & Tubeset	Identical
	12931-13C2 SonicOne SharpVac & Tubeset	Identical
	120-31-10R1 SonicOne Cylindrical Probe & Tubeset	Identical
Probes cleared in K212060	150-32-2120: BoneScalpel Access MIS 20mm Blade & Tubeset	Identical
	150-32-2120: BoneScalpel Access MIS Micro Hook Shaver & Tubeset	Identical
	130-35-5502 SonaStar Shaver, Aspirator & Tubeset Kit	Identical
	120-31-13C3 SonicOne Curette Tip Excel Kit	Identical
Probes cleared in K221235	130-26-2416 SonaStar Elite 1.6mm Micro Long Tip & Tubeset	Identical

	Predicate Device (K221235)	**Subject Device**
	130-26-2498 SonaStar Elite 1.6mm Notched Long Tip & Tubeset	Identical
	130-26-2419 SSE 1.9mm Standard Long Tip & Tubeset	Identical
	130-26-2499 SonaStar Elite 1.9mm Notched Long Tip & Tubeset	Identical
Cleaning and Sterilization of Sterile Single Use Devices	EtO Sterilization Identical Sterilization Cycles	Identical
Shelf-Life Sterile Single Use Devices	3 Years Identical Sterile Barrier Packaging	Identical
Electrosurgery		
Electrosurgery Accessory	100-29-0000 SonaStar Monopolar Handswitch Cable	Identical
Console		
P/N	100-10-0000 neXus Console	Identical
Classification	Class 1 Type BF Applied Part	Identical
Power Input Voltage	100-240 VAC	Identical
Power Input Current	5 A max	Identical
Power Input Frequency	50/60Hz	Identical
Ground Leakage	500 µA (max.)	Identical
Functions	Vibration Irrigation Aspiration	Identical Identical Identical
Vibration System	Continuous Wave Frequency: 22.0-24.5 kHz / Amplitude: up to 355 microns 34.5-37.0 kHz / Amplitude: up to 206 microns	Identical Pulsed Wave, NEW Frequency: Identical Identical
Irrigation pump	Peristaltic pump	Identical

	Predicate Device (K221235)	**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 Identical SonaStar Long and Short Handpieces Identical Bone Scalpel Access Handpiece Identical SonaStar Elite Handpiece Identical
Vacuum Pump	Dual Vacuum Head Pump, 24V	Identical
Vacuum Specification	Min: 2.0 inHg or lower Max: 25 inHg Vacuum Sleep Mode: 0 inHg	Identical Identical Identical
Footswitch	100-50-0000 neXus Wireless Footpedal 100-51-0000 neXus Wired Footpedal	Identical Identical
Console Display	neXus Console with touch screen graphical user interface	Identical

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 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%	Standard Handpiece DEFAULT SETTINGS Identical Identical Identical Identical USER SETTINGS Vibration: Identical Identical Irrigation: Identical Identical Aspiration: Identical Identical SonaStar Handpieces DEFAULT SETTINGS Identical Identical Identical Lap Endo Mode: Identical USER SETTINGS Vibration: Identical Identical Irrigation: Identical Identical Aspiration: Identical5 Identical BoneScalpel Access Handpiece DEFAULT SETTINGS Identical Identical Identical Lap Endo Mode: Identical USER SETTINGS Vibration: Identical Identical Irrigation: Identical Identical

	Predicate Device (K221235)	**Subject Device**
	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 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%	Identical Identical Aspiration: Identical Identical SonaStar Elite Handpiece DEFAULT SETTINGS Identical Identical Identical Lap Endo Mode: Identical 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% DTC (DYNAMIC TISSUE RESPONSE): Incremental adjustment = 1 Range = 1 to 6
Console Software	v1.9 RC2	v1.10 RC0
Dimensions wo/Cart	11.5” H x 16” W x 17” D 292mm H x406 mm W x 432mm D	Identical
Weight wo/Cart	45 lbs. | 20.4 kg	Identical

7. PERFORMANCE DATA

Biocompatibility Testing

Not applicable. There have been no modifications related to patient contacting materials, therefore the biocompatibility testing submitted under K221235 remains valid.

Electrical safety and electromagnetic compatibility (EMC)

No re-testing required. The change to the neXus console is considered a minor software update only. The safety and performance of the device has been validated and verified through software testing in accordance with IEC62304. There have been no device modifications related to the construction of the console or handpiece, therefore the electrical safety and EMC testing submitted under K221235 remains valid.

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 tests were conducted to support the claim of substantial equivalence:

- Tissue removal test using the SonaStar Elite handpiece
- DTC mode vibration test using the SonaStar Elite handpiece

8. CONCLUSION

Subject device modifications do not raise new questions of safety or effectiveness. Technological comparison to the predicate and performance testing on the subject device demonstrates substantial equivalence to the predicate device for the requested intended use.