December 13, 2021

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

Re: K212060
Trade/Device Name: neXus Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: June 29, 2021
Received: November 9, 2021

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

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

510(k) Number *(if known)*

K212060

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 and the indications for the SonaStar® long and short handpiece in combination with SonaStar® probe kit accessory configurations are listed below.

Standard Handpiece with BoneScalpel 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 reception such as segmetectomies, 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 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

Long SonaStar Handpiece & Short SonaStar Handpiece 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
• Urological Surgery
• Plastic and Reconstructive Surgery General Surgery
• Orthopedic Surgery

• Gynecological Surgery except as contraindicated for uterine fibroids.
• Thoracic Surgery
• Laparoscopic Surgery
• 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 Kit
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 reception such as segmetectomies, nonanatomical subsegmentectomies and metastatectomies.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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

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

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the MisonixneXus Ultrasonic Surgical Aspirator System (K212060) is provided below.

## 1. SUBMITTER

Applicant: Misonix Inc.
1938 New Highway
Farmingdale, NY 11735

Contact: John Salerno
Vice President of Regulatory Affairs and Quality Assurance
Misonix Inc.
1938 New Highway
Farmingdale, NY 11735
Main: 631-694-9555
Direct: 631-927-9123
jsalerno@misonix.com

Submission Correspondent: John Salerno
Vice President of Regulatory Affairs and Quality Assurance
Main: 631-694-9555
Direct: 631-927-9123
jsalerno@misonix.com

Date Prepared: November 8, 2021

## 2. DEVICE

| | |
|---|---|
| Device Trade Name: | neXus Ultrasonic Surgical Aspirator System |
| Device Common Name: | Ultrasonic Surgical Aspirator System |
| Classification Name | Unclassified, Pre-amendment |
| Regulatory Class: | Unclassified |
| Product Code: | LFL, GEI |

## 3. PREDICATE DEVICE

Predicate Device: K190160: Misonix neXus Ultrasonic Surgical Aspirator System

## 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 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.

## 5. 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 and the indications for the SonaStar long and short handpiece in combination with SonaStar probe kit accessory configurations are listed below.

**Standard Handpiece with BoneScalpel 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 followingcystic 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 uterusexcept as contraindicated for uterine fibroids.

- **Thoracic Surgery**

  Limited pulmonary reception such as segmetectomies, nonanatomical subsegmentectomies and metastatectomies.

- **Wound Care**

  The neXus Ultrasonic Surgical Aspirator is also indicated for use in the debridementof 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 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 debridementof 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**

**Long SonaStar Handpiece & Short SonaStar Handpiece 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
- Urological Surgery
- Plastic and Reconstructive Surgery General Surgery
- Orthopedic Surgery
- Gynecological Surgery except as contraindicated for uterine fibroids.
- Thoracic Surgery
- Laparoscopic Surgery
- 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 Kit**

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 cysticlesions: 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 uterusexcept as contraindicated for uterine fibroids.

- Thoracic Surgery

Limited pulmonary reception such as segmetectomies, nonanatomical subsegmentectomies and metastatectomies.

## 6. SUBSTANTIAL EQUIVALENCE

## Comparison of Indications

| **Subject Device (K212060)**<br>**BoneScalpel® Access Handpiece**<br>***for use with BoneScalpel Access Probe and Tubeset Configurations*** | **Predicate Device (K190160)**<br>**Standard Handpiece**<br>***for use with BoneScalpel Probe and Tubeset Configurations*** |
|---|---|
| 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.<br>The indications for use for the Standard Handpiece in combination with BoneScalpel® and SonicOne® OR probe kit accessory configurations and the indications for the SonaStar® long and short handpiece in combination with SonaStar® probe kit accessory configurations are listed below.<br><br>**<u>Standard Handpiece with BoneScalpel Probe Kits</u>**<br>Indicated for use in the fragmentation and aspiration of soft and hard (e.g.: bone) tissue in the following surgical specialties:<br>• **Neurosurgery**<br>• **Gastrointestinal and Affiliated Organ Surgery**<br>• **Urological Surgery**<br>• **Plastic and Reconstructive Surgery**<br>• **General Surgery**<br>• **Orthopedic Surgery** | 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.<br>The indications for use for the Standard Handpiece in combination with BoneScalpel® and SonicOne® OR probe kit accessory configurations and the indications for the SonaStar® long and short handpiece in combination with SonaStar® probe kit accessory configurations are listed below.<br><br>**<u>Standard Handpiece with BoneScalpel Probe Kits</u>**<br>Indicated for use in the fragmentation and aspiration of soft and hard (e.g.: bone) tissue in the following surgical specialties:<br>• **Neurosurgery**<br>• **Gastrointestinal and Affiliated Organ Surgery**<br>• **Urological Surgery**<br>• **Plastic and Reconstructive Surgery**<br>• **General Surgery**<br>• **Orthopedic Surgery** |

| Subject Device (K212060)<br>**BoneScalpel® Access Handpiece**<br>*for use with BoneScalpel Access Probe and Tubeset Configurations* | Predicate Device (K190160)<br>**Standard Handpiece**<br>*for use with BoneScalpel Probe and Tubeset Configurations* |
|---|---|
| • **Gynecology**<br>**External genitalia** - condyloma - benign tumors (lipomas, fibromas, and leiomyomas) - malignant primaryand metastatic tumors of all types and the following cystic lesions: Bartholin's cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts<br>**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 ascontraindicated for uterine fibroids.<br>• **Thoracic Surgery**<br>Limited pulmonary reception such as segmetectomies,nonanatomical subsegmentectomies and metastatectomies.<br>• **Wound Care**<br>The neXus Ultrasonic Surgical Aspirator is also indicatedfor 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.<br>**Standard Handpiece with SonicOne Probe Kits**<br>Indicated for use in the fragmentation and aspiration of soft and hard tissue (i.e. bone) in the following surgical specialty:<br>• **Wound Care**<br>The neXus Ultrasonic Surgical Aspirator is also indicatedfor 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.<br>• **Plastic and Reconstructive Surgery**<br>**Long SonaStar Handpiece & Short SonaStar Handpiece withSonaStar Probe Kits**<br>Indicated for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue in the following surgical specialties:<br>• Neurosurgery<br>• Gastrointestinal and Affiliated Organ Surgery<br>• Urological Surgery<br>• Plastic and Reconstructive Surgery General Surgery<br>• Orthopedic Surgery<br>• Gynecological Surgery except as contraindicated foruterine fibroids.<br>• Thoracic Surgery<br>• Laparoscopic Surgery<br>• Thoracoscopic Surgery<br>The SonaStar Handpieces may also be combined with electrosurgery using optional RF surgery interface components.<br>**Bone Scalpel Access Handpiece with BoneScalpel Access Probe Kit**<br>Indicated for use in the fragmentation and aspiration of soft and hard (e.g.: bone) tissue in the following surgical specialties:<br>• Neurosurgery<br>• Gastrointestinal and Affiliated Organ Surgery<br>• Urological Surgery<br>• Plastic and Reconstructive Surgery<br>• General Surgery | • **Gynecology**<br>**External genitalia** - condyloma - benign tumors (lipomas, fibromas, and leiomyomas) - malignant primaryand metastatic tumors of all types and the following cysticlesions: Bartholin's cysts, Vestibular adenitis, Inclusion cysts, Sebaceous cysts<br>**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 ascontraindicated for uterine fibroids.<br>• **Thoracic Surgery**<br>Limited pulmonary reception such as segmetectomies,nonanatomical subsegmentectomies and metastatectomies.<br>• **Wound Care**<br>The neXus Ultrasonic Surgical Aspirator is also indicatedfor 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.<br>**Standard Handpiece with SonicOne Probe Kits**<br>Indicated for use in the fragmentation and aspiration of soft and hard tissue (i.e. bone) in the following surgical specialty:<br>• **Wound Care**<br>The neXus Ultrasonic Surgical Aspirator is also indicatedfor 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.<br>• **Plastic and Reconstructive Surgery**<br>**Long SonaStar Handpiece & Short SonaStar Handpiece withSonaStar Probe Kits**<br>Indicated for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue in the following surgical specialties:<br>• Neurosurgery<br>• Gastrointestinal and Affiliated Organ Surgery<br>• Urological Surgery<br>• Plastic and Reconstructive Surgery General Surgery<br>• Orthopedic Surgery<br>• Gynecological Surgery except as contraindicated foruterine fibroids.<br>• Thoracic Surgery<br>• Laparoscopic Surgery<br>• Thoracoscopic Surgery<br>The SonaStar Handpieces may also be combined with electrosurgery using optional RF surgery interface components. |

| Subject Device (K212060)<br>**BoneScalpel® Access Handpiece**<br>*for use with BoneScalpel Access Probe and Tubeset Configurations* | Predicate Device (K190160)<br>**Standard Handpiece**<br>*for use with BoneScalpel Probe and Tubeset Configurations* |
|---|---|
| • Orthopedic Surgery<br>• Gynecology<br>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<br>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 ascontraindicated for uterine fibroids.<br>• Thoracic Surgery<br>Limited pulmonary reception such as segmetectomies, nonanatomical subsegmentectomies andmetastatectomies. | |

## Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate device (Misonix neXus Ultrasonic Surgical Aspirator System, K190160).

**Table 1: Technological Comparison**

| | Subject Device | Predicate Device (K190160) |
|---|---|---|
| **Classification Product Code** | LFL | LFL |
| **Subsequent Product Code** | GEI | GEI |
| **Console Classification** | Class 1<br>Type BF Applied Part | Class 1<br>Type BF Applied Part |
| **Power Input Voltage** | 100-240 VAC | 100-240 VAC |
| **Power Input Current** | 5 A max | 5 A max |
| **Power Input Frequency** | 50/60Hz | 50/60Hz |
| **Ground Leakage** | 500 µA (max.) | 500 µA (max.) |
| **VibrationSystem** | Continuous WaveFrequency:<br>22.0-24.5 kHz<br><br>Amplitude:<br>up to 355 microns | Continuous WaveFrequency:<br>22.0-24.5 kHz<br><br>Amplitude:<br>up to 355 microns |

| | Subject Device | Predicate Device (K190160) |
|---|---|---|
| **Irrigation Flow Rate** | Adjustable between:<br>Min: 1-3 ml/min<br>and<br>Max: 67-85 ml/min | **Standard Handpiece:**<br>BoneScalpel and SonicOne related Applications, adjustable between:<br>Min: 12-18 ml/min<br>and<br>Max: 67-85 ml/min<br><br>**SonaStar Short Handpiece:**<br>SonaStar related Applications, adjustable between:<br>Min: 1-3 ml/min<br>and<br>Max: 9-14 ml/min |
| **Vacuum Pump** | Min: 2.0 inHg or lower<br>Max: 25 inHg<br>Vacuum Sleep Mode: 0 inHg | **Standard Handpiece**:<br>Not applicable<br><br>**SonaStar Short Handpiece**:<br>Min: 2.0 inHg or lower<br>Max: 25 inHg<br>Vacuum Sleep Mode: 0 inHg |
| **Footswitch** | Wireless<br>On/Off Pedal for ultrasound, irrigation, and aspiration<br>-Linear amplitude control with the degree of pedal depression<br>Flush button<br><br>Wired<br>(Connected to right-hand side of the panel of console), Single pedal footswitch to activate delivery of ultrasoundand irrigation. | Wireless<br>On/Off Pedal for ultrasound, irrigation and aspiration<br>-Linear amplitude control with the degree of pedal depression<br>Flush button<br><br>Wired<br>(Connected to right-hand side of the panel of console), Single pedal footswitch to activate delivery of ultrasoundand irrigation. |
| **Console Display** | neXus Console with touch screen graphical user interface | neXus Console with touch screen graphical user interface |
| **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 |

# 7. PERFORMANCE 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).

Thefollowing biocompatibility testing was provided for the subject device.The following testing was completed:

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

## Sterilization and Shelf Life

Single Use Disposable Components - provided Sterile

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

- Probe Tip assembly: titanium horn + tip, available in various sizes and types, some areprovided 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. The sterilization method is unchanged from K190160.

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

**Accelerated 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. In addition, real time aging studies for 13**

**months were provided. Real time aging studies at 37-months will also be conducted and the protocol was provided.Electrical safety and electromagnetic compatibility (EMC)**

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

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012
- IEC 60601-1-2:2014
- IEC 60601-2-2: 2017

There are no significant differences between the predicate device, K190160, and the subject device, as relates to compliance with IEC 60601-1:2005, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.*

There are no significant differences between the predicate device, K190160, and the subject device, as relates to compliance with IEC 60601-1-2:2014, *Medical electrical equipment - Part1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*. Based on the analysis, emissions and immunity compliance of the neXus system are unaffected with the BoneScalpel Access handpiece, thus no further EMC testing was required.

IEC 60601-2-2:2017, *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* does not apply to the subject device; however, applies to the predicate neXus Ultrasonic Surgical Aspirator System with the SonaStar Long and Short Handpieces (K190160) combined with electrosurgery using optional RF surgery interface components.

## 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 o

Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as 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:

- Ultrasound Performance Testing
- Acoustic Intensity Testing
- Applied Part Temperature Testing – Normal and Abnormal Operating Conditions
- Hard Tissue Performance Testing
- Thermal Testing of Simulated Bone Tissue on BoneScalpel Access Handpiece and Tips

## 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.

# 8. CONCLUSION

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