May 30, 2019

Misonix, Inc.
John Salerno
VP RA/QA & CCO
1938 New Highway
Farmingdale, New York 11735

Re: K190160
Trade/Device Name: neXus Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, GEI
Dated: May 7, 2019
Received: May 8, 2019

Dear John Salerno:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-

combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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

Sincerely,

for

Jennifer R. Stevenson
Acting Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190160

Device Name
Misonix Inc. 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
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.

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

1. SUBMITTER

Applicant: Misonix Inc.
1938 New Highway
Farmingdale, NY

Contact: John Salerno
VP RAQA & CCO
Misonix Inc.
1938 New Highway
Farmingdale, NY 11735
Main: 631-694-9555
Direct: 631-927-9123
jsalerno@misonix.com

Date Prepared: May 6, 2019

2. DEVICE

Name of Device:	Misonix® Inc. neXus® Ultrasonic Surgical Aspirator System
Common or Usual Name:	Ultrasonic Surgical Aspirator System
Classification Name:	Unclassified
Regulatory Class:	Pre-Amendment, 510(k)
Product Code:	LFL - instrument, ultrasonic surgical
Secondary Product Code:	GEI - electrosurgical, cutting & coagulation & accessories
FDA Panel:	General and Plastic Surgery

3. PREDICATE DEVICE

Predicate Device:	K070313 - AUSS-7 Ultrasonic Surgical Aspirator System
Secondary Predicate Device:	K062471 - FS 1000 RF Ultrasonic Surgical Aspirator

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. 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 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.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The neXus system’s indications for use statement is equivalent to the indications for use cleared for the of the predicate devices. Like the predicate devices, the neXus system is indicated for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue.

The surgical specialties for neXus are a combination of the surgical specialties for both predicates and are specified by handpiece.

Technological Comparisons

The table below compares the key technological feature of the subject devices to the predicate devices.

Table 1: Technological Comparison

	Subject Device	**Primary Predicate Device (K070313)**	**Secondary Predicate Device (K062471)**
510(k) Number	K190160	K070313	K062471
Device Name	neXus Ultrasonic Surgical Aspirator System	AUSS-7 ULTRASONIC SURGICAL ASPIRATOR SYSTEM	FS 1000 RF
Classification Regulation	Unclassified	Unclassified	Unclassified
Classification Product Code	LFL – Ultrasonic Surgical Instrument	LFL – Ultrasonic Surgical Instrument	LFL - Ultrasonic Surgical Instrument
Subsequent Product Code	GEI - Electrosurgical, cutting & coagulation & accessories	N/A	GEI - Electrosurgical, cutting & coagulation & accessories
Console Classification	Class 1 Type BF Applied Part	Class 1 Type B Applied Part	Class 1 Type B Applied Part
Power Input Voltage	100-240 VAC	100-130 VAC 6.5 Amps, 50/60 Hz 200/250 VAC 2.25 Amps, 50/60 Hz	115 VAC 230 VAC
Power Input Current	5 A max	6.5 A at 100-130 VAC, 3.25 A at 200/250 VAC	4 A max
Power Input Frequency	50/60Hz	50/60Hz	50/60Hz
Ground Leakage	500 µA (max.)	300 µA (max.)	300 µA (max.)

	Subject Device	Primary Predicate Device (K070313)	Secondary Predicate Device (K062471)
Vibration System	Continuous Wave Frequency: 22.0-24.5 kHz Amplitude: up to 355 microns	Continuous Wave Frequency: 22.5Khz Amplitude: Up to 300 microns	Continuous Wave Frequency: 23+/-1 kHz or 22-24 kHz Amplitude: up to 355 microns
Irrigation pump	Peristaltic pump	Peristaltic pump	Peristaltic pump
Pump Flow Rate	BoneScalpel and SonicOne related Applications, adjustable between: Min: 12-18 ml/min and Max: 67-85 ml/min SonaStar related Applications, adjustable between: Min: 1-3 ml/min and Max: 9-14 ml/min	BoneScalpel and SonicOne related Applications: Flow is adjustable, 0-100ml/min	SonaStar related Applications: Up to 10cc/min
Vacuum Pump	Min: 2.0 inHg or lower Max: 25 inHg Vacuum Sleep Mode: 0 inHg	Max: 28” Hg Max	Min: less than 0.5” Hg Max: 25” Hg
Footswitch	Wireless - On/Off Pedal for ultrasound, irrigation and aspiration -Linear amplitude control with the degree of pedal depression - Flush button	Wired (connected to rear panel of console), Single pedal footswitch to activate delivery of ultrasound and irrigation	Wired - On/Off Pedal for amplitude, irrigation and aspiration - Flush Button - COAG with CUT lockout feature - COAG simultaneous with ultrasound - COAG only
Console	nexus Console with touch screen graphical user interface	Console with membrane control panel and graphical user interface	Console with membrane control panel and LED indicators.

	Subject Device	Primary Predicate Device (K070313)	Secondary Predicate Device (K062471)
Dimensions wo/Cart	11.5" H x 16" W x 17" D | 292mm H x406 mm W x 432mm D	7" H x 16" W x 19" D | 180mm H x 410 mm W x 685mm D	40" H x 25" W x 19" D | 102 cm H x 63.5 cm W x 48 cm D
Weight wo/Cart	45 lbs | 20.4 kg	25.6 lbs | 11.6 kg	120 lb. | 54.5 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, with limited contact (≤ 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, with limited contact (≤ 24h).

The patient contacting components of the **neXus** system are the ultrasonic tip (and sheath, when applicable), which 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).

Biocompatibility testing (Cytotoxicity, Irritation, Sensitization, System Toxicity, and Pyrogenicity) was performed in accordance with the following standards:

- ISO 10993-1 Fourth edition 2009-10-15
- ISO 10993-5 Third edition 2009-06-01
- ISO 10993-7 Second edition 2008-10-15
- ISO 10993-10 Third edition 2010-08-01
- ISO 10993-11 Second edition 2006-08-15
- ISO 10993-12:2012 Fourth edition 2012-07-01

Sterilization and Shelf Life

Single Use Disposable Components - provided Sterile

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

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

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

The submission includes the required sterilization information per FDA guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile" issued January 21, 2016.

The submission also includes sterile barrier testing and device performance testing on sterilized and accelerated aged devices to support a shelf life of 3 months.

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.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device in accordance with the following standards:

- ANSI/AAMI/ES 60601-1:2005 + A2:2010 + A1:2012
- IEC 60601-2-2: 2017
- IEC 60601-1-2: 2014

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered 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 performance testing demonstrated that the device continues to meet all of the specifications and requirements that were met by the predicate devices:

- Ultrasound Performance Testing
- Irrigation Performance Testing
- Aspiration Performance Testing
- OEM RF Compatibility
- Wireless Coexistence 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.

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. The modifications made to the system to combine the features of the primary predicate (the AUSS-7 cleared in K070313) and the secondary predicate (the FS 1000 RF cleared in K062471) into one universal platform do not change its intended use and do not raise new questions of safety or effectiveness. The biocompatibility test results demonstrate that the patient and fluid path contacting materials are biocompatible. The EMC and Electrical Safety test results demonstrate that the neXus system meets the applicable requirements for this device type. The software documentation and test results demonstrate that the neXus system has been fully verified and validated for its intended use. And finally, the performance test results demonstrate that the specifications and requirements of the subject device are substantially equivalent to the specifications and requirements of the predicate devices. Therefore, the subject device can be found substantially equivalent to the predicate devices.