July 15, 2022

Integra LifeSciences Corporation
Alexandra Wells
Senior Regulatory Specialist
1100 Campus Rd
Princeton, New Jersey 08540

Re: K221763
Trade/Device Name: CUSA Clarity Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, LBK
Dated: June 16, 2022
Received: June 17, 2022

Dear Alexandra Wells:

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

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

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

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

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

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

Sincerely,

for

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

Enclosure

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)*
To Be Determined

Device Name
CUSA® Clarity Ultrasonic Surgical Aspirator System

Indications for Use *(Describe)*

The CUSA® Clarity Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable.

The CUSA Clarity Ultrasonic Surgical Aspirator is indicated for use in:

Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses:

Neurosurgery - including removal of primary and secondary malignant and benign brain and spinal tumors, including but not limited to meningiomas and gliomas

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

General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures

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

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.

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	1100 Campus Rd, NJ 08540 USA
Phone Number	1-609-903-6300
Establishment Registration Number	9004007
Name of Contact Person	Alexandra Wells
Date Prepared	June 15, 2022
807.92(a)(2) – Name of device	
Trade or Propriety Name	CUSA® Clarity Ultrasonic Surgical Aspirator System
Common or Usual Name	Ultrasonic Surgical Aspirator
Classification Name	Instrument, Ultrasonic Surgical
Classification Panel	General and Plastic Surgery
Regulation	Unclassified
Product Code(s)	LFL, LBK
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
CUSA® Clarity Ultrasonic Surgical Aspirator System K200774 CUSA® Excel+ Ultrasonic Surgical Aspirator System K141668	

807.92(a)(4) - Device description

The devices within the scope of this premarket notification are the CUSA® Clarity 23kHz Laparoscopic Tip Packs that are intended to be used with the 23 kHz Handpiece of the CUSA® Clarity Ultrasonic Surgical Aspirator System.

The CUSA® Clarity Ultrasonic Surgical Aspirator System is the newest device that was added to the Integra Lifesciences Corporation family of tissue ablation products. There are three (3) systems currently marketed in the United States: CUSA Clarity Ultrasonic Surgical Aspirator System (CUSA Clarity), CUSA® Excel+ Ultrasonic Surgical Aspirator System (CUSA Excel+) and CUSA® NXT Ultrasonic Tissue Ablation System (CUSA NXT). All CUSA systems are surgical aspirators that use ultrasonics and cavitation, in combination with irrigation and aspiration, to fragment, emulsify and remove unwanted tissue. It allows for the selective dissection of target tissue while preserving vessels, ducts, and other delicate structures.

The CUSA Clarity 23kHz Laparoscopic Tip Packs have the same intended use and technological characteristics as the predicate CUSA Clarity and CUSA Excel+ systems, including the predicate tip pack accessories. The primary modification of the subject tips compared to the predicate devices is that they are longer, in order to provide an alternate tip design suited for laparoscopic surgery to the CUSA Clarity portfolio. CUSA Clarity is already indicated for laparoscopic surgery. The purpose of the subject tips is to continue to fill out the CUSA Clarity Tip portfolio to align with that of the legacy CUSA Excel+ system and meet user needs; the CUSA Excel+ system has a tip design very similar to the subject tips. Additionally, testing confirmed that the modifications reduce the frictional force between a trocar and the flue as compared to the predicate CUSA Excel+ Laparoscopic Tip, making the device easier to insert and retract from the trocar during surgical use.

807.92(a)(5) – Intended use of the device

Indications for Use	The CUSA® Clarity Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable. The CUSA Clarity Ultrasonic Surgical Aspirator is indicated for use in: Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses: Neurosurgery - including removal of primary and secondary malignant and benign brain and spinal tumors, including but not limited to meningiomas and gliomas 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 General Surgery – including removal of benign or malignant tumors or other unwanted soft tissue in open or minimally invasive general surgical procedures 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

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate
The CUSA Clarity 23 kHz Laparoscopic Tip Packs have the same technological characteristics compared to the predicate device. The primary modification of the CUSA Clarity 23 kHz Laparoscopic Tip Packs compared to the predicate devices is that they are longer, in order to provide an alternate tip design suited for laparoscopic surgery to the CUSA Clarity portfolio. CUSA Clarity is already indicated for laparoscopic surgery. The purpose of the CUSA Clarity 23 kHz Laparoscopic Tip Packs is to continue to fill out the CUSA Clarity tip portfolio to align with that of the legacy CUSA Excel+ system and meet user needs. The device is maintaining the same underlying technology and intended use of previous CUSA systems. Thus, the majority of the features and technology of the CUSA Clarity 23 kHz Laparoscopic Tip Packs are not new for a CUSA device and benefit from longstanding safety and/or efficacy.
807.92(b)(1-2) – Nonclinical and clinical tests submitted

Non-clinical testing was performed to ensure the safety and efficacy of the CUSA Clarity 23 kHz Laparoscopic Tip Packs. Testing included, but was not limited to:

- Sterilization, Shipping and Stability testing per FDA guidance documents and recognized standards
- Biocompatibility testing per FDA guidance documents and recognized standards
- EMC and Electrical Safety testing per FDA guidance documents and recognized standards
- Bench testing to verify requirements including those listed below:
    - Tissue fragmentation rate
    - Tip life with CEM
    - Torque functionality during assembly
    - Functionality within specification during environmental variations
    - Mechanical and performance testing
    - Trocar-Flue friction testing
    - Thermal Effects and Capacitive Coupling per FDA guidance document

No clinical studies were required or performed as all conducted performance tests appropriately support a determination of substantial equivalence compared with the predicate devices.

807.92(b)(3) – Conclusions drawn from non-clinical and clinical data

The results of the non-clinical testing indicate that the intended use of the device, fundamental scientific technology, and performance of the CUSA Clarity 23 kHz Laparoscopic Tip Packs are substantially equivalent to the predicate devices.