



August 22, 2022

Integra Lifesciences Corporation  
Alexandra Wells  
Senior Regulatory Specialist  
1100 Campus Road  
Princeton, New Jersey 08540

Re: K221835

Trade/Device Name: CUSA Clarity Ultrasonic Surgical Aspirator System

Regulatory Class: Unclassified

Product Code: LFL, LBK

Dated: June 22, 2022

Received: June 23, 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](mailto: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

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

### Indications for Use

510(k) Number (if known)

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.

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Integra LifeSciences Corporation - Traditional 510(k)  
CUSA® Clarity 23 kHz Single-Sided Bone Tip Packs

**SECTION 5 - 510(K) SUMMARY**

Integra LifeSciences Corporation – Traditional 510(k)  
 CUSA® Clarity 23 kHz Single-Sided Bone Tip

### 510(k) SUMMARY

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

<b>807.92(a)(1) – Submitter information</b>	
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 21, 2022
<b>807.92(a)(2) – Name of device</b>	
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
<b>807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed</b>	
CUSA® Clarity Ultrasonic Surgical Aspirator System K200774	

Integra LifeSciences Corporation – Traditional 510(k)  
CUSA® Clarity 23 kHz Single-Sided Bone Tip

**807.92(a)(4) - Device description**

The device within the scope of this premarket notification is the CUSA® Clarity 23kHz Single-Sided Bone Tip Pack that is 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. 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 Single-Sided Bone Tip Pack has the same intended use and technological characteristics as the predicate CUSA Clarity system, including all predicate tip pack accessories. A bone tip is currently cleared with the predicate CUSA Clarity system (CUSA Clarity 23 kHz Bone Tip). The primary modification of the CUSA Clarity 23 kHz Single-Sided Bone Tip Pack when compared to the currently cleared CUSA Clarity bone tip is that the subject device has a limited abrasive fragmentation surface at the distal end of the tip when compared to the existing bone tip.

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

Integra LifeSciences Corporation – Traditional 510(k)  
 CUSA® Clarity 23 kHz Single-Sided Bone Tip

<p><b>Indications for Use</b></p>	<p>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.</p> <p>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:</p> <p>Neurosurgery - including removal of primary and secondary malignant and benign brain and spinal tumors, including but not limited to meningiomas and gliomas</p> <p>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</p> <p>Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy</p> <p>General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures</p> <p>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</p>
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Integra LifeSciences Corporation – Traditional 510(k)  
CUSA® Clarity 23 kHz Single-Sided Bone Tip

	appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy
<b>807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate</b>	
<p>The CUSA Clarity 23 kHz Single-Sided Bone Tip Pack has the same technological characteristics compared to the predicate device. The main purpose of this submission is to continue the effort to fill out the CUSA Clarity tip portfolio to align with the legacy CUSA systems. The device is maintaining the same underlying technology and intended use of previous CUSA systems. Thus, the features and technology of the CUSA Clarity 23 kHz Single-Sided Bone Tip Pack are not new for a CUSA device and benefit from longstanding safety and/or efficacy.</p>	
<b>807.92(b)(1-2) – Nonclinical and clinical tests submitted</b>	



Integra LifeSciences Corporation – Traditional 510(k)  
CUSA® Clarity 23 kHz Single-Sided Bone Tip

Non-clinical testing and/or predicate testing adoptions were performed to ensure the safety and efficacy of the CUSA Clarity 23 kHz Single-Sided Bone Tip Pack as well as substantial equivalence with the predicate device. The testing and adoptions included, but were not limited to:

- Sterilization, shipping and stability per FDA Guidance documents and recognized standards
- Biocompatibility per FDA Guidance documents and recognized standards
- EMC and Electrical Safety per FDA Guidance documents and recognized standards
- Bench testing to verify requirements including those listed below:
  - Tissue fragmentation rate
  - Tip life
  - Torque functionality during assembly
  - Functionality within specification during environmental variations
  - Mechanical and performance testing

No clinical studies were performed or required 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 Single-Sided Bone Tip Pack is substantially equivalent to the predicate device.