July 11, 2024

Integra LifeSciences Corporation
Karen Monaghan
Senior Regulatory Affairs Specialist
1100 Campus Rd Princeton
Princeton, New Jersey 08540

Re: K240493
Trade/Device Name: CUSA® Clarity Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, LBK
Dated: February 16, 2024
Received: May 13, 2024

Dear Karen Monaghan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240493

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 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
Gynecological Surgery – including removal of dysplastic genital or perianal epithelial tissue including vulvar and vaginal intraepithelial neoplasia, removal of condyloma, debulking of metastatic uterine, ovarian, fallopian tube or primary peritoneal carcinoma, and open or laparoscopic excision of tissue and adhesions associated with endometriosis

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.

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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 Princeton, NJ 08540 USA
Phone Number	+353-87-710-5565
Name of Contact Person	Karen Monaghan
Date Prepared	10-July-2024
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	None
Classification Panel	General and Plastic Surgery
Regulation	Unclassified
Product Code(s)	LFL (Instrument, Ultrasonic Surgical), LBK (Neurosurgical Ultrasonic Instruments)
807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
CUSA Clarity Ultrasonic Surgical Aspirator: K182809 The predicate K182809 has not been subject to a design-related recall.	
807.92(a)(4) – Device description	
The CUSA Clarity Ultrasonic Surgical Aspirator System (CUSA Clarity) is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The CUSA Clarity consists of a console that provides power and control of the ultrasonic, aspiration and irrigation functions, two surgical handpieces that provide ultrasonic mechanical energy (23 kHz and 36 kHz), a footswitch to allow user control over the ultrasonics, titanium surgical tips (variety of models), irrigation flues, suction/irrigation system (manifold tubing and vacuum canister) and accessories used for assembly/disassembly and reprocessing. The CUSA Clarity may also be optionally used with the CUSA Electrosurgical Modules which provide	

optional electrosurgical capability.	
807.92(a)(5) – Intended use of the device	
Indications for Use	The Indications for Use for the CUSA® Clarity Ultrasonic Surgical Aspirator System are listed below. When compared to the predicate, the Indications for Use Statement for gynecological surgery has been modified to include specific indications in addition to the previously cleared general indication. There have been no other changes to the Indications for Use when compared to the predicate. 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, 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 Gynecological Surgery – including removal of dysplastic genital or perianal epithelial tissue including vulvar and vaginal intraepithelial neoplasia, removal of condyloma, debulking of metastatic uterine, ovarian, fallopian tube or primary peritoneal carcinoma, and open or laparoscopic excision of tissue and adhesions associated with endometriosis
807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate	
The technological characteristics of the device are the same compared to the predicate device. There are no technological or design changes in the subject device compared to the predicate device. The change included in this submission is an addition of the specific gynecological surgery indication.	
807.92(b) (1-2) – Nonclinical and clinical tests submitted	
No non-clinical testing was provided as the subject device design was not modified from the predicate device. The labeling is developed in accordance with the FDA guidance, “Product Labeling for	

Certain Ultrasonic Surgical Aspirator Devices."

An analysis of peer-reviewed articles on the use of CUSA in Gynecological Surgeries was provided as clinical evidence to support the revision to the indications for use of CUSA in Gynecological surgery (1,465 patients in 54 articles published between 1988 and 2023).

Specifically, in the literature, CUSA was used to treat 272 patients with dysplasia or condyloma, 630 patients requiring debulking procedures, and 18 patients with endometriosis. CUSA was able to perform the procedures effectively with desired treatment outcomes.

Likewise, in condyloma cases, CUSA was successful in achieving desired treatment outcomes. In the clinical literature, use of CUSA also did not result in significant postoperative complications or scarring.

The provided articles demonstrated the safe and effective use of CUSA in debulking ovarian cancer, as well as metastases from endometrial cancer, tubal adenocarcinoma, and peritoneal tumors. Articles reported both increased and decreased procedure durations when CUSA was used. One article noted risk of DIC (Disseminated Intravascular Coagulation); however, no other studies found such a risk of DIC in a CUSA population of 1,465 patients.

In cases where endometrial tissue was removed, CUSA effectively removed the endometrial tissue while preserving vessels and nerves.

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

The information from the peer reviewed clinical literature supports that the subject device is as safe and effective as the predicate device and supports a determination of substantial equivalence.