October 8, 2025

Integra LifeSciences Corporation
Alexandra Wells
Regulatory Affairs Manager
1100 Campus Rd
Princeton, New Jersey 08540

Re: K251162
Trade/Device Name: CUSA® Clarity Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, LBK
Dated: May 6, 2025
Received: May 6, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.08 14:24:47 -04'00'

Colin Kejing Chen
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251162

Please provide the device trade name(s).

CUSA® Clarity Ultrasonic Surgical Aspirator System

Please provide your Indications for Use below.

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
- Cardiac Surgery - including debridement of unwanted tissue in cardiac surgeries including valve replacement and valve repair

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251162

510(k) Summary

Prepared on: 2025-09-09

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Integra LifeSciences Corporation
Applicant Address	1100 Campus Rd Princeton NJ 08540 United States
Applicant Contact Telephone	609-903-6300
Applicant Contact	Ms. Alexandra Wells
Applicant Contact Email	alexandra.wells@integralife.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	CUSA® Clarity Ultrasonic Surgical Aspirator System
Common Name	Ultrasonic Surgical Aspirator
Classification Name	Unclassified
Regulation Number	Unclassified
Product Code(s)	LFL, LBK

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K182809	CUSA® Clarity Ultrasonic Surgical Aspirator System	LFL

Device Description Summary 21 CFR 807.92(a)(4)

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 (CUSA Clarity CEM Nosecones) which provide optional electrosurgical capability.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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
• Cardiac Surgery - including debridement of unwanted tissue in cardiac surgeries including valve replacement and valve repair

Indications for Use Comparison 21 CFR 807.92(a)(5)

The proposed Indications for Use for the CUSA® Clarity Ultrasonic Surgical Aspirator System are listed below. When compared to the currently cleared CUSA Clarity System, the Indications for Use statement has been updated with the addition of the Cardiac Surgery indication. The addition of Cardiac Surgery to the CUSA Clarity Indications for Use statement does not alter the intended use of fragmentation, emulsification and aspiration of tissue using ultrasonic aspiration, as the device will continue to be used for the same purpose simply in cardiac procedures.

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
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• 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
• Cardiac Surgery - including debridement of unwanted tissue in cardiac surgeries including valve replacement and valve repair

Technological Comparison 21 CFR 807.92(a)(6)

The subject CUSA® Clarity Ultrasonic Surgical Aspirator System has the same technological characteristics compared to the predicate device. There is no change to the device or its technological characteristics within scope of this premarket notification.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

No non-clinical testing was provided as the modification was limited to an indications expansion.

The clinical evidence supporting the use of the CUSA® Clarity Ultrasonic Surgical Aspirator System (CUSA Clarity) in cardiac surgeries includes a Systematic Literature Review and a Retrospective Chart Review Real-World Data (RWD) Study.

The CUSA literature demonstrates that surgeons have favorable opinions of the safety and performance of CUSA when used as a tool to remove unwanted tissue in cardiac procedures, and the safety and clinical performance of CUSA is generally on par, and in some cases superior to, comparator devices and/or traditional tools used to remove unwanted tissue in cardiac procedures.

Of the safety outcomes that were assessed, rates of relevant complications that may have resulted from the use of Integra CUSA devices were very low (0.00 to 1.75%; 7 studies, 352 patients). Notably, the upper limit of the complication range derives from a single study, with a single incident. Although hospital stay appeared to be longer after surgery with Integra CUSA devices (16.2±3.9 to 28±11 days) than with comparator devices (4.3±1.4 days), the duration for Integra CUSA devices is based on 3 studies involving 114 patients, whereas that of the comparator devices is based on only 1 study with 5.4-fold fewer patients in total.

Rates of specific complications were 0.00% for both operative deaths and paravalvular leaks for Integra CUSA devices (7 studies, 352 patients, and 3 studies, 186 patients, respectively). Infections ranged from 0.00% to 10.53% (3 studies, 109 patients) with Integra CUSA devices, which is similar to the 10.37% (1 study, 164 patients) observed when conventional tools were used. Notably, none of the authors implied that the infections were related to the use of CUSA.

Performance outcomes were highly dependent on the severity and condition of the cardiac tissue as well as the complexity of the surgery. Total operative times ranged widely; however, the debridement procedure itself, when performed with Integra CUSA devices, took on average less than 15 min of the total operative time. Rates of success (i.e., no more than mild regurgitation, no paravalvular leakage, or other valve dysfunctions at follow-up) were 100.0% (3 studies, 34 patients) when patients underwent surgery with an Integra CUSA device.

While the choice of procedure depends on multiple factors, it should be noted that operative mortality rates are significantly higher after replacement than after repair, irrespective of the devices or tools used. However, compared with traditional surgical tools, such as scalpels and rongeurs, Integra CUSA devices may offer advantages of easier and faster surgery; especially in the case of valve repair.

In summary, the literature suggests that Integra CUSA devices, such as CUSA Clarity, are safe and effective in cardiac surgeries requiring the removal of unwanted tissue.

The Retrospective Chart Review RWD Study demonstrates that the pre-established acceptance criteria were met, and that there were no device-related adverse events reported when CUSA Clarity was used as a tool to remove unwanted tissue in cardiac surgeries.

Operative mortality, as defined by the Society of Thoracic Surgeons Adult Cardiac Surgery Database (STS ACSD), was selected as the primary endpoint of the RWD Study as it is objectively measurable and one of the few unequivocal outcomes to measure. Of the 580 patients analyzed, operative mortalities reported were 1/299 (0.3%) for valve replacement surgeries, and 2/281 (0.7%) for valve repair surgeries. The acceptance criteria, derived directly from the STS ACSD, were met for both valve replacement and valve repairs.

The exploratory endpoint of the RWD was the number of patients with device- or procedure- related adverse events. Of the 580 patients analyzed, there were zero (0.0%) serious intra-operative adverse events related to the product or procedure. There were 11 (1.8%) reported intraoperative adverse events, but none of them were reported to be device-related (0.0%).

In addition to the primary and exploratory endpoints, 97.8% of respondents stated that CUSA Clarity was able to remove tissue that enabled successful valve repair or successful placement of a new valve. Operative times, cross clamping times, and bypass times ranged from less than 100 minutes to greater than 500 minutes. When applicable, post-operative valve areas reported were greater than pre-operative valve areas, suggesting that CUSA was successfully used to remove unwanted tissue and open stenotic areas.

In summary, the RWD Study results support the safety and effectiveness of CUSA Clarity when used to remove unwanted tissue in cardiac surgeries.

In totality, the clinical evidence available supports the safety and effectiveness of CUSA Clarity use as a tool to remove unwanted tissue in cardiac procedures and confirms that no new questions of safety or effectiveness are raised.