June 23, 2020

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

Re: K200774
Trade/Device Name: CUSA Clarity Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, LBK
Dated: March 24, 2020
Received: March 25, 2020

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,

Adam Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200774

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.

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	609-936-2311
Establishment Registration Number	9004007
Name of Contact Person	Alexandra Wells
Date Prepared	June 23, 2020
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; K182809	
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.	
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 neurosurgery 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, 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
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.	
807.92(b) (1-2) – Nonclinical and clinical tests submitted	
No non-clinical testing was required as the design itself was not modified. The clinical evidence used to support the revision to the neurosurgical indication for use is provided from peer-reviewed clinical literature. An analysis of peer-reviewed articles on the use of CUSA in neurosurgical procedures presents clinical evidence to support the indications for use of CUSA in neurosurgery. 72 articles discuss neurosurgical cases in which CUSA was used (reported on approximately 1,706 cases), including the debulking and resection of brain stem tumors, spinal tumors, and brain tumors of a variety of types. Overall, the literature demonstrated that CUSA can be safely	

and effectively used in neurosurgery. The literature showed CUSA to be useful for the resection of tumors ranging from soft to firm consistencies. The benefits described by the authors include enhanced tissue selectivity, preservation of healthy tissue, and more efficient debulking and resection. CUSA has been utilized in neurosurgical applications for over 40 years; and the literature shows CUSA to be safe and effective in neurosurgery including removal of primary and secondary malignant and benign brain and spinal tumors, including but not limited to meningiomas and gliomas.

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

The information from the peer-reviewed clinical literature supports the proposed changes from general to specific indication in neurosurgery and the subject device is substantially equivalent to the predicate device.