DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 6, 2014

Integra LifeSciences Corporation
Mr. Timothy Connors
Regulatory Affairs Specialist
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K141674
Trade/Device Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL, LBK
Dated: September 26, 2014
Received: September 29, 2014

Dear Mr. Connors:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INTEGRA
LIMIT UNCERTAINTY

Indications for Use

510(k) Number (if known): K141674

Device Name:

CUSA® Excel+ Ultrasonic Surgical Aspirator System

Indications For Use:

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery
- Thoracoscopic Surgery

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Integra ▪ 311 Enterprise Drive, Plainsboro, NJ 08536
609-275-0500 ▪ 800-654-2873 toll free ▪ 609-275-9445 fax ▪ integralife.com

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	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	609-275-0500
Fax Number	781-238-0645
Establishment Registration Number	3003418325
Name of Contact Person	Timothy Connors
Date Prepared	June 11, 2014
807.92(a)(2) – Name of device	
Trade or Propriety Name	CUSA® Excel+ 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® Excel Ultrasonic Surgical Aspirator System K981262 CUSA® Excel Ultrasonic Surgical Aspirator System with Bone Tip K051947	
807.92(a)(4) - Device description	
The CUSA Excel+ Ultrasonic Surgical Aspirator System is the current iteration of the previously cleared CUSA Excel Ultrasonic Surgical Aspirator System. Both product lines are owned by Integra LifeSciences; only the CUSA Excel+ is currently marketed in the United States. Like the CUSA Excel, the CUSA Excel+ is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. Minor modifications have been made to the device since the original CUSA Excel was cleared. The intended use and the fundamental scientific technology of the CUSA Excel+ are the same as the CUSA Excel.	

807.92(a)(5) – Intended use of the device	
Indications for Use	The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable: • Neurosurgery • Gastrointestinal and Affiliated Organ Surgery • Urological Surgery • Plastic and Reconstructive Surgery • General Surgery • Orthopedic Surgery • Gynecological Surgery • Thoracic Surgery • Laparoscopic Surgery • Thoracoscopic Surgery

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The CUSA Excel+ has the same technological characteristics compared to the predicate device, the CUSA® Excel. There were minor modifications made to the design of the console and to the sterilization method and manufacture of some accessories available for use with the CUSA Excel+. The modifications did not affect the performance specifications, mode of user operation, patient contacting materials, indications for use, or the energy source when compared to the predicate device.

807.92(b)(1-2) – Nonclinical and clinical tests submitted

Non-clinical testing was performed to support modifications, ensuring the safety and effectiveness was maintained following device modifications. Testing included:

- Sterilization validations
- Electromagnetic Compatibility and Electrical Safety testing
- Noise reduction testing
- Non-patient contacting material change testing
- Power supply re-work testing

807.92(b)(3) – Conclusions drawn from non-clinical and clinical data
All modifications have been assessed, both individually and cumulatively, and do not affect the safety and effectiveness of the device, including the intended use of the device, the fundamental scientific technology and the performance specifications of the CUSA® Excel+. The CUSA Excel+ is substantially equivalent to the predicate device.