DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2016

Alliqua Biomedical, Inc.
Kathy Simpson
Director, QA/RA
11495 Valley View Road
Eden Prairie, Minnesota 55344

Re: K162721
Trade/Device Name: Stimucel System, Stimucel Generator, Stimucel Treatment Wand, Stimucel Applicator
Regulation Number: 21 CFR 878.4410
Regulation Name: Low Energy Ultrasound Wound Cleaner
Regulatory Class: Class II
Product Code: NRB
Dated: November 28, 2016
Received: December 2, 2016

Dear Kathy Simpson:

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" (21 CFR 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162721

Device Name
UltraMIST

Indications for Use *(Describe)*
MIST Systems produce a low energy ultrasound generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates, and bacteria.

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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510k Summary

510(k) Summary (As required by 21 CFR §807.92)	
Submitter	Alliqua BioMedical, Inc. 11495 Valley View Road Eden Prairie, MN 55344
Contact Person:	Kathy Simpson Director QA / RA Telephone: 952-224-8738 Fax: 952-224-8797 Email: ksimpson@alliqua.com
Date Prepared:	August 29, 2016
Trade Name of Device:	UltraMIST™
Common / Usual Name:	UltraMIST™
Classification Name:	Low Energy Ultrasound Wound Cleaner Class: II Regulation: 21 CFR §878.4410
Product Code:	NRB
Manufacturer:	Alliqua BioMedical, Inc. 11495 Valley View Road Eden Prairie, MN 55344
Establishment Registration:	3004580659
Predicate Device(s):	K140782, UltraMIST® System Manufacturer: Alliqua BioMedical, Inc.
Device Description:	MIST Systems (e.g., UltraMIST System) are low frequency ultrasound devices, which utilize a fluid (e.g., saline) mist to deliver the ultrasound to the treatment site. The atomized fluid allows the treatment to be performed without direct contact to the patient. MIST Systems are made up of a main generator component, treatment wand, and disposable applicator. MIST Systems deliver low-frequency ultrasound to the treatment site using an atomized fluid mist. The mist is generated from a small, portable system consisting of a generator, a treatment wand (encasing an ultrasound transducer), and a disposable applicator that has been designed to connect to a user-provided fluid source (e.g., IV saline bag). The system provides a flow of fluid (irrigant) to the tissue surface by the use of low frequency, low intensity ultrasound. Only the mist touches the tissue, not the ultrasound radiation surface (horn tip), thus the term “non-contact” ultrasound. The flow of fluid as an irrigant is controlled by a peristaltic pump on the generator unit. The fluid is dispensed onto the ultrasound radiation surface where the mist is generated. The mist is projected by fundamental atomization or nebulization and acoustic streaming or acoustic radiation force respectively.
Intended Use:	The intended use of the MIST Systems is for the delivery of low energy ultrasound via a fluid mist for the promotion of wound healing. It is a prescription use only device. The overall target market for MIST Systems is the advanced wound care

<table>
<tr><td></td><td>market. There have been no changes to the intended use of the subject of this submission.</td></tr>
<tr><td>Indications for Use</td><td>MIST Systems produce a low energy ultrasound generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria.</td></tr>
<tr><td>Summary of Technical Comparisons:</td><td>A summary of the technical components of the subject device and the predicate UltraMIST System are presented in the Table below:
<table>
<tr><th>Technical Component</th><th>UltraMIST System</th><th>Subject Device</th></tr>
<tr><td>Control of Fluid Flow</td><td>Clamp on tubing line to stop and start fluid flow for priming purposes.
Peristaltic pump used to provide consistent flow</td><td>Same</td></tr>
<tr><td>Enclosures</td><td>Injection molded PC/ABS polymer and compound curvature</td><td>Geon HC 8210, Rigid Polyvinyl Cyholride, Flammability rated V-0</td></tr>
<tr><td>Supply Voltage and Current</td><td>100-240VAC Universal input</td><td>Same</td></tr>
<tr><td>Input Frequency</td><td>50-60Hz Universal input</td><td>Same</td></tr>
<tr><td>Rated Power</td><td>100 watts (fuse limited)</td><td>Same</td></tr>
<tr><td>Distal Displacement of Radiation Surface</td><td>65 ± 10 microns</td><td>Same</td></tr>
<tr><td>Acoustic Frequency</td><td>40 ± 1 kHz</td><td>Same</td></tr>
<tr><td>Radiation Surface Diameter and Material</td><td>0.390 in. ± 0.001 in.
Titanium alloy (TI-6AL-4V)</td><td>Same</td></tr>
<tr><td>Single patient Use Disposable Applicator</td><td>Injection molded PC/ABS polymer and compound curvature</td><td>Same</td></tr>
<tr><td>Packaging and Labeling</td><td>System: Non-sterile, reusable
Applicator: Sterile per ISO 11607</td><td>Same</td></tr>
<tr><td>Method of Sterilization</td><td>Gamma radiation</td><td>Same</td></tr>
<tr><td>Shelf Life / Product Life Cycle</td><td>System: 5 years
Applicator: 3 years</td><td>Same</td></tr>
<tr><td>Mode of Exudate and Bacterial Removal</td><td>Atomized mist
Acoustic and fluid stream delivery / washout</td><td>Same</td></tr>
<tr><td>Microprocessor</td><td>Yes</td><td>Same</td></tr>
<tr><td>Patient contact</td><td>None – fluid contact only via atomized mist</td><td>Same</td></tr>
<tr><td>Treatment variables</td><td>Treatment duration based on area to be treated (algorithm)</td><td>Same</td></tr>
<tr><td>Software modifications</td><td>Alarm limits for detecting</td><td>Alarm limits</td></tr>
</table>
</td></tr>
</table>

	– Generator v0.8	current out of range narrower than original MIST System	modified to be equivalent to that of the original MIST System
Performance Data – Non-Clinical Testing:	Testing performed on the subject device to demonstrate Substantial Equivalence: • IEC 60601-1 3rd Ed. General Safety Testing –Testing was performed by Intertek to verify that the change in enclosure material for the Generator and Treatment Wand did not have an adverse effect on the safety or performance of the system. The results of the testing demonstrated that the system with the new material enclosures was as safe, as effective, and performed as well as the predicate device with the previous enclosure materials. The complete test report is included in the submission materials and can be found in VOL_16, Appendix C. • Biocompatibility testing, Cytotoxicity – Testing was performed by WuXi AppTec to verify that the change in enclosure material for the Generator and the Treatment Wand did not have an adverse effect on the biocompatibility of the system. Since the Generator and Treatment Wand do not come into contact with a breached or compromised surface, or potential indirect contact with a breached or compromised surface like the Applicator, only Cytotoxicity testing was performed to ensure that the new enclosure materials do not present a new or different biocompatibility issue for the user of the device. The results of the testing demonstrated that the new enclosure materials for the Generator and Treatment wand were as safe, as effective, and performed as well as the previous enclosure material as both were determined to be non-cytotoxic.The complete test report is included in the submission materials and can be found in VOL_15, Appendix B. • Consensus standards used in the testing and preparation of this premarket notification may be found in VOL_005, Standards Data Report Forms.		
Clinical Studies:	NA for this submission.		
Conclusions:	The modifications made to the subject device are substantially equivalent to its predicate, the UltraMIST System.		