March 16, 2018

Restoration Robotics, Inc.
Raymond Lee
Vice President of Regulatory Affairs and Quality Assurance
128 Baytech Drive
San Jose, California 95134

Re: K173358
Trade/Device Name: ARTAS System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ONA
Dated: February 15, 2018
Received: February 16, 2018

Dear Raymond Lee:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173358

Device Name

ARTAS System

Indications for Use *(Describe)*

The ARTAS System from Restoration Robotics is indicated for harvesting hair follicles from the scalp in men diagnosed with androgenic alopecia (male pattern hair loss) who have black or brown straight hair. The ARTAS System from Restoration Robotics is intended to assist physicians in identifying and extracting hair follicular units from the scalp during hair transplantation; creating recipient sites; and implanting harvested hair follicles.

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.

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SECTION 5
510(K) SUMMARY

510(k) Summary

I. SUBMITTER

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Date Prepared: 10/24/2017

II. DEVICE

Name of Device: ARTAS System
Regulatory Description: Stereotaxic Instrument
Regulation Number: 21 CFR 882.4560
Device Class: 2
Product Code: ONA
Trade Name: ARTAS System

III. PREDICATE DEVICE

ARTAS System, K123548
***(Reference Device**: CAPSTONE Spinal System K103731)*

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IV. DEVICE DESCRIPTION

The ARTAS System is used under the control of a physician to assist with the harvesting of follicular units and recipient site creation steps of the hair transplantation process. Follicular units are harvested from the patient's scalp, and then implanted into the patient's scalp in the recipient sites created by the physician or the ARTAS System. Additionally, the modified ARTAS System has the capability to assist the physician with the implantation step of the hair transplantation procedure.

The ARTAS System is an interactive, image-guided, computer assisted system consisting of several main subsystems. These include a robotic arm, imaging, needle mechanism, safety, computer, accessory kits and patient chair. The ARTAS System Cart houses the Robotic Arm, the Needle Mechanism, the Imaging subsystems and the Computer. The Needle Mechanism houses the Accessory Kits required for harvesting, recipient site creation, and implantation. The Needle Mechanism is mounted on the Robotic Arm which is mounted on the System Cart. The robotic arm controller is built into the cart and controls the robot and is connected to the computer for communications and transmission of movement instructions. The Accessory Kits contain components necessary to complete the hair transplantation procedure, including the accessories for harvesting, site-making, and implantation.

The Accessory Kits used with the ARTAS System and Procedures include Disposable and Reusable Accessory Kits. For Implantation, the Implant Accessory Kits are used with the modified ARTAS System. The ARTAS Mechanism holds equivalent commercially available components of the predicate device. The Implantation Needle Assembly is inserted into the ARTAS Needle Mechanism with a pre-loaded 'Linear Cartridge' with hair follicles prior to implantation. Restoration Robotics has also incorporated an 'Index Cam-Obturator Assembly' which facilitates the progression of the Linear Cartridge to the next available hair follicle. The Fiducial Platform provides a location for fiducial markings used to track target locations during the Site Making and Implantation Procedures. All items must be sterilized prior to use.

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V. INDICATIONS FOR USE

The ARTAS System from Restoration Robotics is indicated for harvesting hair follicles from the scalp in men diagnosed with androgenic alopecia (male pattern hair loss) who have black or brown straight hair. The ARTAS System from Restoration Robotics is intended to assist physicians in identifying and extracting hair follicular units from the scalp during hair transplantation; creating recipient sites; and implanting harvested hair follicles.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The predicate ARTAS System was designed to assist physicians in the harvesting of hair follicles and creation of recipient sites for hair transplantation. The predicate ARTAS system was previously cleared under K123548. Restoration Robotics has made design modifications to the predicate ARTAS System to assist the physician with hair follicle implantation process during hair transplantation. Both the current ARTAS System and modified ARTAS System utilize the same computer-assisted techniques to orient and actuate the motorized arm which is equipped with the appropriate harvesting, site-making, or implantation accessory kit.

The modified ARTAS System simultaneously creates recipient sites and implants the harvested hair follicles one at a time. The modified ARTAS System controls the implantation depth through a combination of the software vision sub-system, and two independent touch sensors. Implantation parameters include puncture depth, density, angle, hair caliber and implant depth. Harvested follicles are loaded into the Linear Cartridge which is then inserted into the Implant Body Assembly to perform Implantation. Conventional technique of manual hair transplantation uses forceps to implant the harvested hair follicles. Following implantation of all follicular units, the manual technique and the modified ARTAS System use similar action of inspecting all follicles and making adjustments as needed.

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The Vision Subsystem has been modified to accommodate the required implantation images necessary for the implantation step of the hair transplantation procedure. There have been no other changes made to the Vision Subsystem as was originally cleared in K103428, and subsequently cleared K123548.

VII. PERFORMANCE DATA

Verification and Validation Testing was conducted to verify the functionality of Implantation and all safety related features as well as the integration of the modified ARTAS System software and hardware controls. Implantation functional attributes of the modified ARTAS System were evaluated for each attribute, the overall system performance and associated subsystem operations were verified to ensure that the design output met the design input criteria. All test results met the acceptance criteria and documented in the test reports. During the Risk Management process, each hazard with potential failure modes was identified and the appropriate mitigations were developed through the Failure Mode and Effect Analysis (FMEA) process. Following mitigations, all potential risks were deemed acceptable. The modified ARTAS System has been determined to be safe for its intended use.

A non-significant risk FDA approved clinical study was performed under Investigational Device Exemption (IDE) G160117 to validate the performance of the ARTAS System. The study was entitled, "Computer-Assisted Hair Implantation Using ARTAS System vs. Manual Implantation Technique: Hair Restoration Study". The purpose of this clinical study was to investigate and compare the safety and effectiveness of the ARTAS™ System to manual hair follicle implantation method following a nine-month period of post-procedure evaluation. During this study two equal size (2cm x 3cm) implantation target areas were identified on the patients' scalp. A total of 140 hair follicles were implanted with one method (ARTAS or manual) into one target area. Another set of the same type of hair grafts were implanted with the other method into the second target area. (The order of implantation was randomized).

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The primary efficacy endpoint was the difference in the number of implanted terminal hair follicles that survived in the target area with manual implantation minus the number of implanted terminal hair follicles that survived in the target area with computer-assisted implantation. The hypothesis tested was one of non-inferiority. The mean difference between manual implanted arm minus the ARTAS implanted arm at Month 9 was 8.2 ± 17.23 hair follicles which represent 5.9% ± 12.3% of total hairs transplanted. The result of the statistical analysis using a non-inferiority margin of fourteen (14) hair follicles which represents 10% of 140 follicles transplanted, provide statistical proof that the survival of hair follicles implanted using the ARTAS system method was non-inferior to the manual implanted method, with one-sided 95% confidence. Therefore, the primary efficacy endpoint of this study was achieved.

		Manual side	**ARTAS side**	**Difference in number of hairs (Manual side – ARTAS side)**		
				Number	%	P value
Number of follicles assigned to recipient site		70 follicles (140 hairs) per subject	70 follicles (140 hairs) per subject	--	--	--
Intraprocedural implantation success rate (%)		Not recorded	92%	--	--	--
9-month recipient site hair count change from baseline (N= 30 subjects)	Mean	91.4 hairs	83.2 hairs	8.2 hairs	5.9 ± 12.3 %	0.0386
	Min	21	27	--	--	--
	Max	135	130	--	--	--
Implantation procedure time		Not recorded	70 follicles (140 hairs) / 9 minutes	--	--	--

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There were no adverse events reported during this study. All reported post-operative symptoms were assessed by the principal investigator and determined not to be an adverse event but common side effects that are typically expected after hair transplantation procedure. In every case symptoms that the patients experienced affected both implantation areas equally.

In conclusion, the implanted terminal hair follicle survival rate of the ARTAS System was non-inferior to the currently used manual implantation method and the safety of the two methods was similar.

Biocompatibility Testing was conducted for the Implant Disposable and Implant Reusable Accessory Kits of the modified ARTAS System. The Implant Needle of the Implant Disposable Accessory Kit and the Index Cam-Obturator Assembly of the Implant Reusable Accessory Kit are made of 304 Stainless Steel (304SS), a commonly known material currently used to manufacture needles. Additionally, this material is the same as the material used for the Needles of the Disposable Accessory Kits of the predicate ARTAS System (K123548). For the Poly-ether-ether-ketone (PEEK) material, cytotoxicity testing was conducted at Nelson Laboratories (Salt Lake City, UT) as per ISO 10993. The results from these tests demonstrate that PEEK is biocompatible.

A Steam Sterilization Process Validation was conducted for the new components of the Implant Accessory Kits. The Steam Sterilization Validation Test Report for the Implant Disposable and Reusable Accessory Kits documents the testing conducted to a SAL of 10^{-6} using the pre-vacuum and/or gravity steam sterilization procedure. The acceptance criteria for this validation were met and the results were documented in the Test Report. The validated steam sterilization parameters are provided in the Instructions for Use of the Implant Accessory Kits.

Electromagnetic Compatibility (EMC) Testing and Electrical Safety Testing were conducted on the ARTAS System in accordance with the following standards:

- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012, Medical electric equipment Part1: General requirements for safety

Additional EMC Testing was conducted on the Implant Mechanism of the modified ARTAS System. The device test conditions for EMC and Electrical Safety did not deviate from the accepted standard. All test conditions were performed as outlined by the IEC and ANSI/AAMI standards. Electrical Safety and EMC Testing were previously performed by Safety Engineering Laboratory on the predicate ARTAS System. The modified ARTAS System did not require any changes to the electronics, including circuitry, boards, or hardware that involve electricity except for the implantation tool mechanism. The inclusion of the proposed implantation tool does not require any changes to the main system electrical circuitry, therefore electrical safety and EMC testing was conducted on the modified ARTAS Mechanism and previous 60601-1-2 testing remains valid.

VIII. CONCLUSIONS

The principles of operation and technological characteristics remain the same between the predicate ARTAS System and the modified ARTAS System. The modifications to the ARTAS System do not raise new issues of safety and efficacy. The proposed indications for use for the modified ARTAS System is substantially equivalent to the indications for use of the predicate ARTAS System. In terms of its intended use, technological characteristics, safety and performance, the modified ARTAS System is substantially equivalent to the predicate ARTAS System from Restoration Robotics.