510(k) SUMMARY

510(k) Notification (K) K123154

GENERAL INFORMATION

Applicant:
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U.S.A.
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Date Prepared: October 3, 2012

DEVICE INFORMATION

The ARTAS™ System from Restoration Robotics ("ARTAS™ System") 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.

The ARTAS™ System implements the manual Follicular Unit Extraction (FUE) approach to harvesting follicular units. The ARTAS™ System is used, under the direction of a physician, to automate the manual FUE technique. The ARTAS™ System is positioned over the patient's scalp by the physician and follicular units are identified. Follicular units are then harvested from the patient's scalp. The follicular units are stored until they are implanted into the patient's scalp by the physician or technician using current manual implantation techniques.

Classification:
21CFR§882.4560, Stereotaxic Instrument

Product Code:
ONA

Trade Name:
The ARTAS™ System from Restoration Robotics

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Generic/Common Name:
Stereotaxic Instrument

PREDICATE DEVICES

The ARTAS™ System is substantially equivalent to the following predicate device:

- ARTAS™ System, K103428

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.

PRODUCT DESCRIPTION

The ARTAS™ System implements the manual Follicular Unit Extraction (FUE) approach to harvesting follicular units. The ARTAS™ System is used, under the direction of a physician, to automate the manual FUE technique. The ARTAS™ System is positioned over the patient's scalp by the physician and follicular units are identified.

Follicular units are then harvested from the patient's scalp. The follicular units are stored until they are implanted into the patient's scalp by the physician or technician using current manual implantation techniques.

The ARTAS™ System is an interactive, image-guided, computer-assisted system consisting of seven main subsystems:

1. Robotic Arm Subsystem
2. Imaging Subsystem
3. Needle Mechanism
4. Safety Subsystem
5. Computer
6. Accessory Kits (Disposable and Reusable)
7. Patient Chair

These main subsystems, with the exception of the Accessory Kits and Patient Chair, are housed on or within a Control Cart.

TECHNOLOGICAL CHARACTERISTICS

The predicate ARTAS™ System provided left and right screen views on the monitor during the harvesting procedure. The left screen provided a view of the current follicle being harvested and the right screen a view of the next follicle selected for harvest. The present modified ARTAS™ System provides a single, larger view of the follicle being harvested and a map view of the entire field of harvest.

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The predicate ARTAS™ System that was cleared by FDA in April 2011, (K103428) required harvesting parameters to be manually entered by the user by keying in numbers using a PC keyboard. The present system that is the basis of this submission incorporates toggle arrows for processing parameters on the computer monitor allowing a much simpler means by which to vary these parameters. This improvement in ease of use was validated clinically.

The modified ARTAS™ System has been productized for cost reduction and manufacturability resulting in a system that is much more mobile than the predicate ARTAS™ System. The improvements made in the system mobility along with the mechanism changes were validated clinically.

Auto Hair Selection

The predicate ARTAS™ System followed a harvesting process in which the system would move after completing a harvest and then highlight the next follicle for harvest. The present modified ARTAS™ System highlights the next follicle for harvest while harvesting the initial follicle.

The predicate ARTAS™ System required the user to adjust the direction of harvest for subsequent harvests once the needle completed a grid row. The present modified system recognizes the end of a row and changes direction automatically although, the user can still change the direction at any time. This change was made possible by incorporating fiducial markers on the skin tensioner that is applied to the patient scalp. This change improves the ease of use and was validated clinically.

Disposable Kit

Several changes in the disposables have been implemented in the present modified version of the ARTAS™ System from the disposables included for the predicate system. The disposables used with the predicate ARTAS™ System were provided non-sterile with instructions on how to sterilize the disposables using an autoclave. The present disposable kit included with the modified ARTAS™ System is provided gamma sterilized. This process has been validated in accordance with ANSI/AAMI/ISO 11137 and 11737 standards.

The change to provide the disposable kit sterile in the modified ARTAS™ System submission requires that the present disposable kit bear a "Use By Date" that ensures sterility for a minimum of one (1) year. This shelf life was validated in accordance with ASTM F1980-07.

A design change was made to the punch used in the modified ARTAS™ System resulting in a more reliable punch. This change was validated clinically.

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NONCLINICAL TEST SUMMARY

Extensive testing was performed on the subject device to support a determination of substantial equivalence to the predicate device. This testing included software verification and validation, patient chair verification, system cart verification, and disposable and reusable verification. All required electrical safety tests including EMC (IEC-60601-1 and IEC60601-1-2) were also performed. Biocompatibility testing was performed on all patient contacting materials for the disposable and reusable components.

The testing referenced above includes all of the tests that were performed on the predicate device. Since the results were identical for these tests, substantial equivalence has been demonstrated through these nonclinical tests.

CLINICAL TEST SUMMARY

A clinical study was performed on ninety-two (92) patients using the modified ARTAS™ System. Primary efficacy (transection rates and non-implantable follicles) as well as safety endpoints were met.

SUBSTANTIAL EQUIVALENCE

The indications for use for the modified ARTAS™ System is substantially equivalent to the indications for use of the predicate ARTAS™ System (K103428). Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the modified ARTAS™ System is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench (mechanical, electrical, software performance, and biocompatibility testing) and clinical testing was conducted on the modified ARTAS™ System to support a determination of substantial equivalence to the predicate device.

SUMMARY

The modified ARTAS™ System is substantially equivalent to the predicate device, ARTAS™ System (K103428) cleared on April 4, 2011.

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

Restoration Robotics, Incorporated
% Mr. Jim Talbot
Senior Director, Quality and Regulatory Affairs
128 Baytech Drive
San Jose, California 95134

February 19, 2013

Re: K123154
Trade/Device Name: The ARTAS™ System from Restoration Robotics
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: ONA
Dated: January 25, 2013
Received: February 01, 2013

Dear Mr. Talbot:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123154

Device Name: The ARTAS™ System from Restoration Robotics

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.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -S

Digitally signed by Long H. Chen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -S, 0.9.2342.19200300.100.1.1=13003690 56
Date: 2013.02.19 14:42:17 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123154