

FEB 25 2013

RESTORATION ROBOTICS, INC.

THE ARTAS™ SYSTEM FROM RESTORATION ROBOTICS

**510(k) SUMMARY**

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*P1074*

**510(k) Notification K123548**

**GENERAL INFORMATION**

**Applicant:**

Restoration Robotics  
128 Baytech Drive  
San Jose, Ca 95134  
U.S.A.  
Phone: 408-883-6760  
FAX: 408-883-6889

**Contact Person:**

Jim Talbot  
Restoration Robotics  
128 Baytech Drive  
San Jose, Ca 95134  
U.S.A.  
Phone: 408-883-6760  
FAX: 408-883-6889

**Date Prepared:** November 1, 2012

**DEVICE INFORMATION**

**Trade Name:**

The ARTAS System from Restoration Robotics

**Generic/Common Name:**

Stereotaxic Instrument

**Classification:**

21CFR§882.4560, Stereotaxic Instrument

**Product Code:**

ONA

**510(k) SUMMARY**

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**PREDICATE DEVICE(S)**

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

- ARTAS™ System, K103428
- Recipient Site Blades (Manual Surgical Instruments, Regulation No. 878.4800, Class I, exempt)

**INTENDED 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. The ARTAS System is also indicated for creating recipient sites for subsequent manual implantation of the harvested follicles.

**PRODUCT DESCRIPTION**

The ARTAS™ System implements the manual Follicular Unit Extraction (FUE) approach to harvesting follicular units and has the potential to solve the technical challenges inherent in the manual FUE technique. 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.

Following harvesting, the ARTAS system is positioned over the patient's scalp by the physician and implantation sites are made in the designated area of the scalp.

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.

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**TECHNOLOGICAL CHARACTERISTICS**

The technological characteristics of the ARTAS System from Restoration Robotics are similar to the predicate devices. No changes to the hardware were made to the subject modified ARTAS System, or even to the needle mechanism. Site making is performed simply by replacing one disposable (the harvest needle) with another (the site-making blade).

A new "operation mode" was created within the software for site-making. In this mode you can manually or automatically pick sites within the same tensioner bounds as used by harvesting. The operator can control site density, site depth, and angle at which the blade enters when it makes the site. The software automatically avoids existing hairs exactly as it does during harvest. Other than these few changes, the same software and user interface used by harvesting is used by site-making. Performance Data were provided to support the determination of substantial equivalence.

**SUBSTANTIAL EQUIVALENCE**

The indications for use for the predicate devices (ARTAS System and the Recipient Site Blades) are substantially equivalent to the proposed indications for use for the proposed ARTAS System. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the ARTAS System is substantially equivalent to the predicate device.

**TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION**

All necessary bench and clinical testing was conducted on the ARTAS System to support a determination of substantial equivalence to the predicate device.

**Nonclinical Testing Summary:**

The nonclinical, bench testing included:

- Software verification and validation data
- Hardware design verification data
- Implantation site-making performance testing

The collective results of the nonclinical bench testing demonstrate that the materials chosen, the manufacturing processes, and design of the ARTAS System meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the ARTAS System does not raise new questions of safety or effectiveness when compared to the predicate devices.

**Clinical Testing Summary:**

A multi-center, prospective, blinded, clinical study was performed to compare the safety and effectiveness of the ARTAS System to the manual hair follicle harvesting method following a nine month period of post-procedural evaluation. The clinical study enrolled healthy men, between the ages of 30 and 59, who had brown or black straight hair and a

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clinical diagnosis of androgenetic alopecia (male pattern hair loss). The clinical report generated from this study supported safety and effectiveness of the predicate ARTAS System cleared under 510(k) No. K103428.

An additional safety analysis was performed on the data from this study to demonstrate that the intended use of creating follicular implantation sites do not raise any new issues of safety.

**CONCLUSION**

The ARTAS System from Restoration Robotics shares its design and mechanism of action as the predicate devices. The results of the nonclinical bench and clinical testing demonstrate that the ARTAS System functions to its specifications and performs as intended. The ARTAS System is substantially equivalent to the predicate devices in terms of technology characteristics, intended use, and performance. No new issues of safety or effectiveness are raised.

**SUMMARY**

The ARTAS System is substantially equivalent to the predicate device.



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 25, 2013

Re: K123548

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 30, 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

**INDICATIONS FOR USE STATEMENT**

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510(k) Number (if known): K123548

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. The ARTAS System is also indicated for creating recipient sites for subsequent manual implantation of the harvested follicles.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden   
2013.02.25 10:41:13 -05'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

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