SECTION 5
510(K) SUMMARY (CONT.)

510(k) Notification K103428

GENERAL INFORMATION

Applicant:
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Mountain View, CA 94043
U.S.A.
Phone: 650-965-3612
FAX: 650-965-3624

APR - 4 2011

Contact Person:
Kit Cariquitan
Vice President, Regulatory Affairs
Experien Group, LLC
155-A Moffett Park Drive, Suite 210
Sunnyvale, CA 94089
U.S.A.
Phone: 408-400-0856
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Date Prepared: November 19, 2010

DEVICE INFORMATION

Classification:
21CFR§882.4560, Stereotaxic Instrument

Product Code:

ONA

Trade Name:
The ARTAS™ System

Generic/Common Name:

Stereotaxic Instrument

PREDICATE DEVICES

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

- Medicamat S.A. Calvitron Hair Transplant System, K952737
- Integrated Surgical Systems, Inc. DigiMatch ROBODOC Surgical System, K072629

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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.

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. Follicular units are then identified, dissected and extracted from the surrounding tissue on the patient's scalp by the ARTAS System. The follicular units are transported using suction to a storage container where they 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.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the ARTAS System is substantially equivalent to the indications for use of the Medicamat S.A. Calvitron Hair Transplant 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 devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

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

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Nonclinical Testing Summary:

The nonclinical, bench testing included:

- Electrical Safety and Electromagnetic Compatibility Testing
- Software Verification and Validation Testing
- Hardware Design Verification Testing
- Cytotoxicity Testing

The collective results of the nonclinical 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 for follicular unit extraction when compared to the manual procedure.

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 clinical diagnosis of androgenetic alopecia (male pattern hair loss).

A total of 36 subjects were treated in this study at two U.S. clinical sites. The mean age of the participants was 48.6 ± 7.5. Subjects predominantly had black hair and stage V or VI baldness on the Norwood-Hamilton Classification scale. The population at both sites was similar.

There were no adverse events, serious adverse events or unanticipated adverse events reported by any subjects during the course of this study. All complications were "Mild" in intensity. None of the subjects terminated the study early due to any safety-related issues.

The primary effectiveness endpoint was the difference in the number of surviving implanted hair follicles at Month 9 post-implantation between those implanted hair follicles that were harvested using the ARTAS System and those that were harvested using the manual method of hair harvest. In comparing the implant results by hair follicle harvest method, the ARTAS System was found to be substantially equivalent to the manual harvest method at nine months ($p = 0.023$). The primary effectiveness endpoint of this study was achieved.

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CONCLUSION

As demonstrated in this clinical study, no new issues of safety or effectiveness are raised by implementing computer-assisted techniques for follicular unit extraction as compared to the manual procedure. The nonclinical and clinical testing of the ARTAS System has demonstrated the device to be at least as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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Sunnyvale, California 94089

APR - 4 2011

Re: K103428
Trade/Device Name: The ARTAS™ System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: ONA
Dated: March 21, 2011
Received: March 22, 2011

Dear Kit Cariquitan:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103428

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103428

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 And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (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)

for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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