OCT - 7 2011

VENUSCONCEPT

510(K) SUMMARY

Venus Swan™ System

510(k) Number K 111784

Applicant's Name: Venus Concept Ltd.
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Trade Name: ***Venus Swan™***

Preparation Date: June 20, 2011

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEI
Regulation No: 21 CFR 878.4400
Class: II
Panel: General and Plastic Surgery

Device Description:

The ***Venus Swan™*** System uses Radiofrequency (RF) energy in $(MP)^2$ technology for treatment. $(MP)^2$ technology is a Multi-Polar array of Bi-Polar RF electrodes.

The ***Venus Swan™*** is a modification to the previously cleared Venus Concept's ***Venus Freeze*** system (K100586).

The ***Venus Swan™*** is a non-invasive system consisting of:

- Main Unit (console)
- Touch Screen user interface
- RF Power module
- Controller unit

- Controller unit
- Three optional treatment applicators:

  (1) Octipolar-L™ applicator – for large treatment areas, composed of 8 RF electrodes

  (2) Octipolar-M™ applicator – for medium sized treatment areas, composed of 8 RF electrodes

  (3) Diamondpolar™ applicator – for small treatment areas, composed of 4 RF electrodes

The system can be connected to two applicators only at a time. The user can choose which applicator to use according to the size of the treatment area.

The Touch screen user interface provides:

- Applicator selection
- RF Power Output and Treatment Time parameter adjustments
- Current treatment parameters display.

Controller unit
Three optional treatment applicators
The RF power module provides RF energy to the selected applicator, producing a 1MHz signal.

Intended Use Statement:

The ***Venus Swan*** is a non-invasive device intended for use in Dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No.	Date of Clearance
Venus Freeze	**K100586**	Nov 29, 2010

Performance Standards

Venus Swan complies with the following voluntary standards:

- ***EN 60601-1*** (Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems).
- ***IEC 60601-1-2*** (Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests)
- ***ANSI AAMI 60601-2-2*** for safety of high frequency surgical equipment.

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

Venus Concept Ltd.
% Qsite
Mr. Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

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Re: K111784
Trade/Device Name: Venus Swan™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 22, 2011
Received: September 06, 2011

Dear Mr. Levy:

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

VENUSCONCEPT

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 111784

Device Name: *Venus Swan*

Indications for Use: The ***Venus Swan***™ is a non-invasive device intended for use in Dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General, Restorative and Neurological Devices
510(k) Number

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

510(k) Number K111784