K 110355

510(k) Summary

APR 2 2 2011

Page 1 of 2

Date: January 31, 2011

Submitted by: VENX LLC
2701 NW 2nd Avenue, Suite 218
Boca Raton, FL 33431

Phone: 561-237-5008
Fax: 561-237-5040

Contact: Navroze Mehta

Common Name: Manual Surgical Instrument

Trade Name: **VENX REVOLUTION™**

Classification Name: Manual Surgical Instrument

Classification: Class I per 21 CFR 878.4800

Predicate Device: Advanced Medical Products, Arachnophlebectomy Needle (K000932)

Description:
The **VENX REVOLUTION™** is a sterile, disposable, single patient use surgical instrument for the disruption and destruction of spider veins located in the lower extremities of the body. The device is made available in several sizes to accommodate a range of veins that form in the lower body. The **VENX REVOLUTION™** consists of a thermoplastic handle containing a lever actuated rack and gear mechanism for rotating a shaft extending from the handle. At the end of the shaft are stainless steel, needle-like tines sharpened and spaced appropriately to straddle veins located just below the surface of the skin. Once the tines are in place straddling the vein, the levers are actuated causing the shaft to rotate approximately 360° or more. Actuating the levers causes internal springs to compress. Once the levers have rotated the shaft 360° and the tines have disrupted the vein, releasing the levers allows the compressed springs to return the tines to their original position. The device is then withdrawn and re-inserted at another position within the clinician-selected area to repeat the operation on the same vein or on another vein. The procedure is repeated until all veins within the selected area have been treated.

Intended Use:

The **VENX REVOLUTION™** is a manual surgical instrument intended for use in the destruction of spider veins in the lower extremities of the body.

Comparison to Predicate Devices:

The **VENX REVOLUTION™** differs from the predicate device only in the mechanism for rotating the device tines. The predicate device relied on the clinician to manually rotate the pen-like device within the fingers to disrupt the vein. The **VENX REVOLUTION™**

incorporates a lever-actuated mechanism to rotate the tines a minimum 360° by actuating levers with the fingers. The basic construction, configuration, and available sizes of the tines remain unchanged.

Testing:

Bench testing has been conducted using simulated actual use conditions comparing the new device and its ability to disrupt and destruct spider veins to that of the predicate device. The results of the testing show the new device to perform as intended and equivalent to the predicate device. Testing included tine deformation, cycle life, and rotating mechanism operation.

Conclusion:

In accordance with the Food, Drug, and Cosmetic Act and 21 CFR 807, and based on the information provided in the premarket notification application, VENX LLC concludes that the **VENX REVOLUTION™** is safe, effective and substantially equivalent to the predicate device discussed herein.

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

Venx, LLC
% MRI Medical
Mr. Ira Duesler
4700 S. Overland Drive
Tucson, Arizona 85714

APR 2 2 2011

Re: K110355
Trade Name: Venx Revolution™
Classification Regulation Name and Number: Manual Surgical Instrument for General Use, 21 CFR 878.4800
Regulatory Class: Class I Exempt
Product Code: 79 GAH (Stylet, Surgical, General & Plastic Surgery)
Dated: January 31, 2011
Received: February 7, 2011

Dear: Mr. Duesler

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 878.4800. We suggest that you review this regulation since it may grant other exemptions from certain general controls of the Act. Your device classification regulation name, regulatory class, and product code are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review 21 CFR Section 878.9 to determine whether or not your new device meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact George J.Mattamal, Ph.D at (301) 796-6396 or the Division of Small Manufacturers, International and Consumer Assistance at its

toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,

for

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

Indications For Use

510(k) Number (if known): K110355

Device Name: VENX REVOLUTION™

Indications For Use:

The **VENX REVOLUTION™** is a manual surgical instrument intended for use in the destruction of spider veins in the lower extremities of the body.

Prescription Device X AND/OR Over-The-Counter _____
(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)

N. P. Ogle for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110355