AUG 2 0 2002 K021765

510(k) Summary

General Information

Classification	Class II
Trade Name	VasClip™
Submitter	VMBC, LLC 3600 Labore Road Suite 4 White Bear Lake, MN 55110 651-482-8451
Contact	David Elliot President & CEO

Intended Use

The VasClip is intended for ligation of the vas deferens.

Predicate Devices

K003337	Hem-O-Lok Ligating Clip	Weck Closure Systems

Device Description

The VasClip is a small polymeric self-locking clip that encircles the vas deferens and provides ligation. The device is identical to the Hem-O-Lok device in materials, manufacturing methods and sterilization cycle.

The device is provided sterile and is intended for single use only. It is not intended to be resterilized or reused.

Materials

All materials used in the manufacture of the VasClip are suitable for this use, have been used in numerous previously cleared products and are the same as used in the previously cleared Weck Closure System Hem-O-Lok ligating clip.

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Testing

As the VasClip is identical to the Weck Closure Systems Hem-o-lok ligating clip, no additional testing was required. A study involving 124 men was conducted at a single center. The results of this study confirm the indication for ligation of the vas deferens. This indication is found within the broader indication currently commercialized by Weck Closure Systems in the predicate Hem-o-lok device.

Summary of Substantial Equivalence

The VasClip is identical to the predicate products. The indication for use is within the indications for use of the previously cleared Hem-O-Lok ligating clip indications. Further, the manufacturing procedures, materials and sterilization cycle are identical as well. Therefore, VMBC, LLC believes the VasClip is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2002

Mr. David Elliot, Jr.
President and CEO
VMBC, LLC
3600 LaBore Road, Suite 4
White Bear Lake, Minnesota 55110

Re: K021745
Trade/Device Name: Vasclip
Regulation Number: 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II
Product Code: NJC
Dated: May 24, 2002
Received: May 28, 2002

Dear Mr. Elliot:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The effectiveness of using the Vasclip for permanent male sterilization has not been evaluated in comparison to standard vasectomy procedures.

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); 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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

K021745

Indications for Use

510(k) Number (if known):	This application
Device Name:	VasClip™
Indications for Use:	The VasClip is intended for ligation of the vas deferens.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _ OR Over-The-Counter Use _
(Per 21 CFR 801.109) (Optional Format 1-2-96)