K070661
p. 1 of 2

510(k) Summary

Vitalcor, Inc
100 E. Chestnut Ave
Westmont, IL 60559
(800) 874-8358
630-325-5500
Fax 630-325-0257
Contact: R Gregory Huck, President
Prepared July 21, 2007

AUG 2 9 2007

1. **Identification of the Device**:
   Proprietary-Trade Name: Vitalcor Featherweight Vascular Clamps
   Classification Name/Product Codes: DXC
   Common/Usual Name: Vascular Clamp

2. **Equivalent legally marketed devices**: S&T Micro Anastomosis Clamp, K022754

3. **Indications for Use (intended use)** : These titanium clamps are used for temporarily occlusion of blood vessels during surgery.

4. **Description of the Device**: Vitalcor Featherweight clamps are made from Grade 5 titanium, Vitalcor Featherweight clamps are calibrated to have a clamping pressure that will minimize the possibility of vessel damage. As a guide, the following Vitalcor Featherweight sizes should be used for the vessels size range indicated.

   - VA079-06 0.4mm-1.0mm
   - VA115-09 0.6mm-1.5mm
   - VA140-09 1mm-2mm
   - VA240-18 1.5mm-3mm
   - VA300-24 2mm-4mm
   - VA375-30 3mm-5mm

5. **Comparison to predicate device.** The results of non-clinical and bench testing indicates that the new device is completely comparable to the predicate devices. Biocompatibility and sterilization studies were successfully completed.

6. **Substantial Equivalence Chart**

Item	Predicate S&T, K022754	Vitalcor Featherweight
Indications	The S&T Micro Anastomosis Clamp is a hand held surgical instrument that is designed to be used in Microvascular Surgery to either temporarily occlude or approximate blood vessels during the anastomosis process. The clamps are used to facilitate surgical procedures that are typically called "free flaps" or replants. Once the micro anastomosis has been completed the micro clamp is removed from the patient.	These titanium clamps are used for temporarily atraumatic vascular occlusion of blood vessels during surgery.
Vessel size range	The clamps are available in three different size ranges and are to be used on vessels that range in size from 0.4mm to 2.25mm.	VA079-06 0.4mm-1.0mm VA115-09 0.6mm-1.5mm VA140-09 1mm-2mm VA240-18 1.5mm-3mm VA300-24 2mm-4mm VA375-30 3mm-5mm
Material employed	Stainless steel (multi-use) Plastic (single use)	Titanium only, multi-use
Appearance		
Range of pressure on vessel (Maximum recommended in literature is $30g/mm^2$)	$15g/mm^2$	$15g/mm^2$
Magnetic	Yes (stainless steel)	No (Titanium)
Sterilization	Autoclave presumed	Steam autoclave.

7. **Conclusion**: After analyzing bench and non-clinical testing data, it is the conclusion of Vitalcor that the Featherweight Vascular Clamps are comparable to the predicate device in form and function, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate device. The ability to steam autoclave these clamps was validated by an independent laboratory. Biocompatibility verified by independent lab.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2007

Vitalcor, Inc.
c/o Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K070661
Vitalcor Featherweight Vascular Clamps
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: August 21, 2007
Received: August 24, 2007

Dear Mr. Kamm:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070661

Device Name: Vitalcor Featherweight Vascular Clamps

Indications For Use:
These titanium clamps are used for temporarily occlusion of blood vessels during surgery.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susana R. Vachon
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070661