



Food and Drug Administration  
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September 29, 2017

Gyrus ACMI, Inc.  
Christina Flores  
Senior Specialist, Regulatory Affairs  
136 Turnpike Road  
Southborough, MA 01772

Re: K171440  
Trade/Device Name: Berkeley VC-10 Vacuum Curettage System  
Regulation Number: 21 CFR§ 884.5070  
Regulation Name: Vacuum Abortion System  
Regulatory Class: II  
Product Code: HHI, HHK  
Dated: August 31, 2017  
Received: September 1, 2017

Dear Christina Flores:

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 contact the Division of Industry and Consumer Education (DICE) 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education (DICE) 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,

  
**Charles Viviano -S**

For Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K171440

Device Name

Berkeley VC-10 Vacuum Curettage System

Indications for Use (Describe)

For rapid transcervical aspiration of the uterine cavity.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**K171440**  
**510(k) Summary**  
**Gyrus ACMI, Inc.**  
**Berkeley VC-10 Vacuum Curettage System**

**General Information**

510(k) Submitter	Gyrus ACMI, Inc. 136 Turnpike Rd Southborough, MA 01772 Phone: 508-804-2776
Establishment Registration Number:	3003790304
Contact Person:	Christina Flores Senior Specialist, Regulatory Affairs 508-804-2776 Christina.flores@olympus-osta.com
Date Prepared:	September 27, 2017

**Device Identification**

Classification Name:	Vacuum Abortion System
Regulation number	21 CFR 884.5070
Product codes	HHI (System, Abortion, Vacuum) HHK (Curette, Suction, Endometrial (And Accessories))
Regulatory Class	Class II
Trade Name:	Berkeley VC-10 Vacuum Curettage System
Generic/Common Name:	Vacuum abortion system

**Predicate Device**

K030935	Gyrus ACMI VC-10
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The predicate device has not been subject to a design-related recall.

**Product Description**

The Berkeley VC-10 Vacuum Curettage System uses aspiration to remove uterine contents through the cervix. The system includes the vacuum pump, collection containers, connection tubing, and patient contacting vacuettes. The vacuum pump

is electrically powered and generates suction through vacuum pressure. The vacuum pump console is not provided sterile and is a multi-use device. The patient contacting vacuettes of the VC-10 system are provided as sterile, single use disposable devices.

Similar to the predicate device VC-10, the modified Berkeley VC-10 includes a high capacity, double diaphragm pump and motor, enclosed in a stainless steel cabinet. Collection canisters sit on top of the cabinet, and a large vacuum gauge and vacuum control knob are easily accessed on the top of the cabinet. A vacurette (available in various shapes and sizes) is attached to a collection set (includes a plastic swivel handle with a slip ring to control the vacuum and PVC tubing) and is attached to the patient port of the first collection container. Two accessories, which can be used to collect tissue, include a tissue trap, which is connected to the collection tubing and the collection container, or a gauze sack, which is placed inside the collection container. The modified VC-10 offers the same foot actuator pedal for vacuum supply.

### **Indications for Use**

For rapid transcervical aspiration of the uterine cavity.

The indications for use and intended use of the modified/unmodified Berkeley VC-10 Vacuum Curettage System has not changed as a result of the vacuum pump motor modification in this submission. The indications for use of the subject and predicate devices are identical.

### **Comparison to Predicate Device:**

The modified Berkeley VC-10 has been compared to the predicate VC-10 device with respect to intended use, design, performance, and fundamental scientific technology.

The Berkeley VC-10 was originally cleared in K030935. The modification that is the subject of this submission is to the vacuum pump and motor in the console of the Berkeley VC-10 Vacuum Curettage System. The horsepower rating for the predicate and new vacuum pump is changing from 1/3 horsepower to 1/2 horsepower. All other components of the system are identical to those cleared in K030935. The system's interface with the disposable components has not changed with this modification.

No changes were made to patient contacting material or packaging to the modified VC-10 since the predicate system was cleared in K030935.

A comparison of the pump specifications for the modified Berkeley VC-10 system and the predicate Berkeley VC-10 system is shown in the table below:

	VC-10 (K030935)	VC-10 (this submission)
<b>Motor part number</b>	72R547-V116-D303X	87R647-101-N470X
<b>Voltage/Frequency</b>	115VAC/60 Hz	Same
<b>Power/Amps</b>	600VA/5A	500VA/T6.3AH
<b>Horsepower</b>	1/3 HP	1/2 HP
<b>Maximum Vacuum</b>	73 cm Hg	71 cm Hg

Except for the replacement of a the vacuum pump motor and the adjustments made to the internal enclosure to accommodate the new vacuum pump motor, the modified Berkeley VC-10 system and unmodified Berkeley VC-10 are identical. These minor differences do not raise different questions of safety or effectiveness. As demonstrated in the non-clinical testing (e.g., electrical safety, EMC, and functional testing), the different technological characteristics do not affect the safety and effectiveness of the subject devices. The comparisons and summary of testing results presented in this Special 510(k) Notification show this device to be substantially equivalent to the predicate VC-10 device.

#### **Summary of Biocompatibility, Sterilization and Shelf Life Discussion**

The subject of the modification is the pump motor in the non-patient contacting console of the VC-10 system. The sterile, single use disposable devices that were cleared with the system under K030935 have not been modified since receiving FDA clearance. Therefore, the current submission relies on the biocompatibility, sterilization and shelf life information provided in K030935.

#### **Electrical Safety and Electromagnetic Compatibility (EMC)**

Electrical Safety was tested according to AAMI/ANSI ES 60601-1:2005/(R) 2012 and A1:2012.

EMC was tested according to IEC 60601-1-2 Edition 3: 2007-03.

#### **Summary of Bench. Performance Testing**

The following bench performance tests were conducted to assess the functional performance of the modified device:

- Maximum Measured Vacuum Pressure
- Free Flow Rate
- Time to Develop Vacuum
- Time to Reach Full Vacuum

- Time to Evacuate 1L w/ 7mm Curette
- Time to Evacuate 1L w/ 6mm Curette

All performance testing passed or met the pre-specified acceptance criteria.

### **Conclusion**

The modified Berkeley VC-10 has the same intended use, fundamental technology and similar design as its predicate VC-10 device. The technological differences do not raise different questions of safety or effectiveness and the performance testing demonstrates substantial equivalence.