DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 28, 2015

Utah Medical Products, Inc.
Ben Shirley
VP of Quality Assurance & Product Development
7043 South 300 West
Midvale, UT 84047

Re: K143424
Trade/Device Name: UTAH CVX-RIPE
Regulation Number: 21 CFR 884.4260
Regulation Name: Hygroscopic Laminaria cervical dilator
Regulatory Class: II
Product Code: PFJ
Dated: July 27, 2015
Received: July 29, 2015

Dear Ben Shirley,

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 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 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,

Herbert P. Lerner -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

6.0 Indications for Use Statement

510(k) Number: __K143424_____

Device Name: UTAH CVX-RIPE™; UTMD Cervical Ripening Balloon Catheter

Indications for Use: The UTAH CVX-RIPE™ is intended to mechanically improve the favorability of the cervix of pregnant patients at term gestation, in which induction of labor is medically indicated.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitter Information

510(k) Owner:	Utah Medical Products, Inc.
Address:	7043 South 300 West Midvale, UT 84047 USA
Telephone No.:	(801) 566-1200
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Contact:	Ben Shirley
Contact Phone No.:	(801) 569-4039
Contact E-mail:	bshirley@utahmed.com
Date Prepared:	August 27, 2015

Device Information

Trade Name:	UTAH CVX-RIPE™, UTMD Cervical Ripening Balloon Catheter
Common Name:	Catheter, Balloon, Dilation of Cervix
Classification:	Class II
Regulation:	21 CFR § 884.4260
Description:	Hygroscopic Laminaria cervical dilator
Product Code:	PFJ (catheter, balloon, dilation of cervical canal)

Predicate Device

The predicate device is the Cook® Cervical Ripening Balloon cleared September 27, 2013 under 510(k) number K131206.

Device Description

The UTAH CVX-RIPE™ is a double balloon catheter. The tip is placed through the vagina and into the cervical canal. The distal balloon is positioned against the internal cervical os and inflated with saline. The proximal balloon is positioned against the external cervical os and inflated with saline, providing gradual mechanical cervical dilation by simultaneously applying pressure on the internal and external cervical os. The materials used to manufacture the device, and which have patient contact, are all medical grade silicone.

The UTAH CVX-RIPE™ consists of an 18 Fr., 42 cm silicone catheter with a silicone tip and two silicone balloons. Each balloon is independently inflated via a separate inflation lumen through color coded check valves located at the proximal end of the device. The check valves are marked accordingly, "U" for the distal uterine balloon and "V" for the proximal vaginal balloon. A malleable stainless steel stylet is included for ease of placement. The stylet is placed through a third separate lumen that is closed at the distal tip. The stylet is preloaded in the catheter.

Intended Use

The UTAH CVX-RIPE™ is intended to mechanically improve the favorability of the cervix of pregnant patients at term gestation, in which induction of labor is medically indicated.

Predicate Device Comparison

The UTAH CVX-RIPE™ has the same intended use and technological characteristics as the Cook® Cervical Ripening Balloon cleared under K131206.

Performance Testing

To demonstrate substantial equivalence, the following mechanical performance tests were conducted:

- Balloon Deflation Reliability - Testing to demonstrate that the balloons deflate properly after use.
- Balloon Integrity - Testing to demonstrate that the balloons do not burst at the maximum recommended inflation volume and duration under simulated use conditions.
- Balloon Overuse - Testing to demonstrate that balloons do not leak and properly deflate when using an inflation volume and duration greater than maximum recommendations.
- Balloon Volume Maintenance - Testing to demonstrate that the balloons do not leak.
- Balloon Response to Traction - Testing to demonstrate that the distal balloon does not pull out from the patient under simulated use conditions.
- Bond Strength – Testing to demonstrate that bonded connections do not fail during simulated use conditions.
- Stylet Puncture – Testing to demonstrate that the stylet does not puncture through the catheter during simulated use.

The UTAH CVX-RIPE™ is biocompatible per the requirements of ISO 10993-1.

The shelf life of the UTAH CVX-RIPE™ was established based on the results of an accelerated aging study.

Conclusion

The UTAH CVX-RIPE™ is substantially equivalent to the Cook® Cervical Ripening Balloon cleared under K131206.