January 25, 2023

Aspivix SA
Mauro Rinaldi
Regulatory Affairs and Quality Manager
Chemin du Closel, 5
Renens, Vaud 1020
Switzerland

Re: K223866
Trade/Device Name: Carevix™ Suction Cervical Stabilizer
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: HDC
Dated: December 23, 2022
Received: December 27, 2022

Dear Mauro Rinaldi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Reginald K. Avery -S

for
Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K223866

Device Name
Carevix™ Suction Cervical Stabilizer

Indications for Use *(Describe)*
The Carevix™ Suction Cervical Stabilizer is indicated to snare, grasp, hold and manipulate cervical tissue.

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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510(k) SUMMARY

Submitter:	ASPIVIX SA Chemin du Closel 5 1020 Renens Switzerland
Contact Person:	Mauro Rinaldi, Regulatory Affairs & Quality Manager Telephone: +41 (0) 76 379 87 97 E-mail: mauro.rinaldi@aspivix.com
Date Prepared:	January 23, 2023
Name of Device:	Carevix™ Suction Cervical Stabilizer
Common Name:	Cervical Tenaculum
Product Code:	HDC (Tenaculum, Uterine)
Classification:	Class II
Regulation Name & Number:	21 CFR 884.4530 - Obstetric-gynecologic specialized manual instrument
Predicate Device:	ASPIVIX v1.1 Cervical Suction Tenaculum (K203820) The predicate device has not been subject to a design-related recall.
Description of Device:	Carevix™ Suction Cervical Stabilizer is a sterile, single-use, two-piece device consisting of three main parts: a reloadable vacuum reserve embedded inside the main body, including a piston to generate the vacuum, an activation/deactivation push-button, and an anatomic-shaped suction head to put in contact with the cervix. The suction head includes a rod that connects the main body. The purpose of this submission is to gain clearance for a modified version of the ASPIVIX device. The function and overall use of the Carevix™ Suction Cervical Stabilizer remains the same.
Indication for Use:	The Carevix™ Suction Cervical Stabilizer is indicated to snare, grasp, hold and manipulate cervical tissue.

Comparison of Indications for Use and Technological Characteristics with the Subject and Predicate Device:	**Carevix™ Suction Cervical Stabilizer** **(Subject device)**	**ASPIVIX v1.1** **(Predicate device)**
510(k) number	K223866	K203820
Product Code	HDC	HDC
Indication for Use	The Carevix™ Suction Cervical Stabilizer is indicated to snare, grasp, hold and manipulate cervical tissue.	The ASPIVIX v1.1 Cervical Suction Tenaculum is indicated to snare, grasp, hold and manipulate cervical tissue.
Design	Suction pad (suction head) grasps cervical tissue through vacuum. Handle with one hand. Push button lock.	Suction pad grasps cervical tissue through vacuum. Handle with one hand. Sliding lock.
Material	Polycarbonate/Polyester, thermoplastic elastomer, Methyl methacrylate-Acrylonitrile-Styrene-Butadiene (MABS),	Polycarbonate/Polyester, thermoplastic elastomer, Mixture of methacrylic acid esters and photoinitiator, Polypropylene like material and Triethyl O-acetylcitrate
Sterilization	Yes, e-beam	Yes, e-beam
Single use	Yes	Yes
Differences	The subject Carevix™ Suction Cervical Stabilizer device has the same intended use and principle of operation as the predicate ASPIVIX v1.1 device. However, the device design and materials are different. The design changes include: • An increase in Rod length • An increase in inner diameter of the Rod • A new trigger mechanism • A modified vacuum generation mechanism • The subject device is designed with two-pieces compared to one-piece as in the predicate device. The difference in technological characteristics do not raise different questions of safety and effectiveness.	
Length of Rod	208.85mm	174mm

Inner Diameter of the Rod	2.5mm	1.5mm
Trigger	Push button used to activate and deactivate the vacuum	Frontward-backward slider ring used to deactivate the vacuum
Vacuum	The piston is pulled out from the main body until it reaches the endpoint, generating vacuum.	The rod is pulled out from the body until it stops, generating vacuum.
Technical Characteristic	Two-piece sterile and fully disposable device composed of four parts and three subparts	One-piece sterile and fully disposable device composed of three subparts.
Indications for Use Comparison	The subject and predicate device have the same intended use to snare, grasp, hold, and manipulate cervical tissue.	
Safety and Performance Data:	To support the proposed modifications to the subject device, design control activities and a risk analysis (depicting device change, risk associated, verification method, acceptance criteria, and summary of results) was performed. The Carevix™ Suction Cervical Stabilizer was evaluated according to following verification and validation activities. **Biocompatibility testing** The biocompatibility evaluation for Carevix™ Suction Cervical Stabilizer was conducted following testing protocols used for the predicate device ASPIVIX v1.1 in accordance with the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" in accordance with ISO 14971:2019 - Medical devices – application of risk management to medical devices. Testing included: • Cytotoxicity (ISO 10993-5:2009) • Sensitization (ISO 10993-10:2010) • Vaginal Irritation (ISO 10993-10:2010) The results of testing demonstrated the subject device is non-cytotoxic non-sensitizing, and non-irritating. **Sterilization** The device is provided sterile via irradiation by e-beam. Sterilization validation was performed in accordance with methods equivalent to ANSI/AAMI/ISO 11137-2:2013 and was conducted following testing protocols used for the predicate device ASPIVIX v1.1. **Performance and Safety testing**	

	The tests were performed to assess the performance of Carevix™ Suction Cervical Stabilizer according to the requirements specified in its design and user specifications. All tests were conducted according to the protocols used to validate the predicate device ASPIVIX v1.1. All the results were in accordance with the test acceptance criteria. Safety tests were not conducted as when comparing the *Carevix™* device with the predicate device ASPIVIX v1.1, the newly identified risk pertaining to the assembly of the device does not raise a new question of safety nor effectiveness as this is done before application on the patient and miss-assembly would easily be identified when generating the vacuum prior to use on the patient. Existing risks related to the new sterilization site, changes in the material have been evaluated and no new question of safety or effectiveness is raised based on the tests performed.
Conclusion:	The results of the testing described above demonstrate that the Carevix™ Suction Cervical Stabilizer is as safe and effective as the predicate device and supports a determination of substantial equivalence.