September 3, 2021

Aspivix S.A.
Julien FINCI
CTO & Co-founder
Chemin du Closel 5
Renens, Renens 1020
SWITZERLAND

Re: K203820
Trade/Device Name: ASPIVIX v1.1 Cervical Suction Tenaculum
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HDC

Dear Julien FINCI:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 8/17/21. Specifically, FDA is updating this SE Letter to correct the contact's name as an administrative correction. The issued letter did not reflect the change in contact person that occurred during the agency review.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jason Roberts, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, (240) 402-6400, Jason.Roberts@fda.hhs.gov.

Sincerely,

Jason Roberts -S

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

August 17, 2021

Aspivix S.A.
Benjamin Klein
Regulatory Affairs and Quality Manager
Chemin du Closel
Renens, Renens 1020
Switzerland

Re: K203820
Trade/Device Name: ASPIVIX v1.1 Cervical Suction Tenaculum
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: HDC
Dated: June 28, 2021
Received: July 13, 2021

Dear Benjamin Klein:

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); 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,

Jason Roberts -S

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203820

Device Name
ASPIVIX v1.1 Cervical Suction Tenaculum

Indications for Use *(Describe)*
The ASPIVIX v1.1 Cervical Suction Tenaculum 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Submitter:	ASPIVIX SA Chemin du Closel 5 1020 Renens Switzerland
Contact Person:	Julien FINCI, Regulatory Affairs & Quality Manager Telephone: +41 (0) 76 327 87 97 E-mail: julien.finci@aspivix.com
Date Prepared:	August 10, 2021
Name of Device:	ASPIVIX v1.1 Cervical Suction Tenaculum
Common Name:	Cervical Tenaculum
Device Class:	Class II
Regulation Name & Number:	21 CFR 884.4530 - Obstetric-gynecologic specialized manual instrument
Predicate Device:	K073182 - GYN Disposables INC Tenaculum 356T The predicate device has not been subject to a design-related recall.
Product Code:	HDC, Tenaculum, Uterine
Reference Device:	Bioceptive Suction Cervical Retractor (K142204)
Description of Device:	ASPIVIX v1.1 is a sterile, single-use, one-piece device that consists of four non-removable parts: a reloadable vacuum reserve embedded inside the main body, an activation / deactivation slider ring, a sliding tube to generate vacuum in the main body and an anatomic suction pad to put in contact with the cervix.
Indication for Use:	ASPIVIX v1.1 Cervical Suction Tenaculum is indicated to snare, grasp, hold and manipulate cervical tissue.

Comparison of Technological Characteristics with the Predicate Device:	**ASPIVIX v1.1**	**Tenaculum 356T (Predicate)**
510(k) number	K203820	K073182
Product Code	HDC	HDC
Indication for Use	The ASPIVIX v1.1 Cervical Suction Tenaculum is indicated to snare, grasp, hold and manipulate cervical tissue	Snare, grasp, hold and manipulate cervical and intravaginal tissue
Design	Suction pad grasps cervical tissue trough vacuum. Handle with one hand. Sliding lock.	Two Tips grasp cervical and intravaginal tissue. Handle with two finger holes. Ratcheting lock.
Material	Polycarbonate/Polyester, thermoplastic elastomer, Mixture of methacrylic acid esters and photoinitiator, Polypropylene like material and Triethyl O-acetylcitrate	Glass Reinforced Polycarbonate
Use Environment	Healthcare professional in a healthcare facility	Healthcare professional in a healthcare facility
Sterilization	Yes	Yes
Single use	Yes	Yes
	The differences in technological characteristics do not raise different questions of safety and effectiveness.	
Indications for Use Comparison	The subject and predicate device have the same intended use to snare, grasp, hold, and manipulate cervical tissue.	
Performance Data:	The following performance data were provided in support of substantial equivalence. **Biocompatibility testing** The biocompatibility evaluation for ASPIVIX v1.1 was conducted 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". 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. **Performance Testing** Testing was performed in order to assess the performance and safety of ASPIVIX v1.1 according to the requirements specified in its designs and user specifications. All test results were in accordance with the test acceptance criteria. Testing included release traction force, mechanical traction (pull), bend strength, and tissue safety.
Conclusion:	The results of performance testing described above demonstrate that the ASPIVIX v1.1 is as safe and effective as the predicate device and supports a determination of substantial equivalence.