April 25, 2019

ExCell Company LLC
Jim Snyder
President
1540 West Main Street
Carmel, IN 46032

Re: K182049
Trade/Device Name: ExCellerator Cervical Collection Device
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: Class II
Product Code: HHT
Dated: July 27, 2018
Received: July 31, 2018

Dear Mr. Snyder:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yun-fu Hu -S

for Reena Philip, Ph.D.
Director
Division of Molecular Genetics and Pathology
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182049

Device Name
ExCellerator Cervical Collection Device

Indications for Use *(Describe)*
The ExCellerator Cervical Collection Device is a cervical spatula intended for collecting ectocervical specimens for the ThinPrep Pap test. The device is also intended to be used to aid in a more complete transfer of the specimen material from the endocervical brush (cytobrush) to the PreservCyt solution for ThinPrep testing.
The ExCellerator device must be used with an IVD labeled endocervical brush.

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

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR [807.92(a)(1)]

Date Prepared:	April 23, 2019
510(k) Owner:	ExCell Company LLC 1540 W. Main Street Carmel, IN 46032 317.358.9610 p snyper7x7@gmail.com
Contact:	Jim Snyder – President
Trade Name:	ExCellerator™
Common Name:	Cervical Collection Device (spatula)
Classification Name:	Collector, Cervical Cytological (Obstetric-gynecologic specialized manual instrument)
Device Classification:	Class II
Product Code:	HHT
Predicate Device:	Pap Perfect Plastic Spatula (K861389)

Device Description:
The ExCellerator™ Cervical Collection Device is a non-sterile, single use, disposable cervical sampling device (spatula), comprised of inert food grade polypropylene plastic, intended for sampling the ectocervix during the cervical sample collection procedure.
Additionally, it aids in more complete transfer of the cytological sample collected with an IVD labeled endocervical brush (cytobrush) into the PreservCyt vial for the preparation of ThinPrep Pap test slides.
Use Description:

- The ectocervix is sampled using the ExCellerator cervical cytological spatula. The endocervix is sampled using the IVD labeled endocervical brush.
- The clinician uses both devices as she/he would ordinarily in the manual application of the devices to the ectocervix and endocervix.
- Cells are transferred from the spatula and endocervical brush into liquid preservative (ThinPrep PreservCyt) in accordance with standard protocol.
- Removal of the sample from the endocervical brush is aided by the ExCellerator by utilizing the hole in the device to tease the sample off the brush according to the package insert.

Intended Use:
The ExCellerator Cervical Collection Device is a cervical spatula intended for collecting ectocervical specimens for the ThinPrep Pap test. The device is also intended to be used to aid in a more complete transfer of the specimen material from the endocervical brush (cytobrush), to the PreservCyt solution for the ThinPrep Pap testing.
The ExCellerator device must be used with an IVD labeled endocervical brush.

Indications for Use
See Intended Use above.

Technological Characteristics:
The ExCellerator™ cervical cytological spatula is a standard device in terms of overall design and use, and satisfies the definition of a cytological cervical spatula, which is: "A cytological cervical spatula is a blunt instrument used to scrape and remove cytological materials from the surface of the cervix or vagina." – 21 CFR 884.4530 (a)(13).

The ExCellerator™ cervical cytological spatula is different in one (1) respect. It has an oblong opening "Hole" ~0.250 x 0.130-in. in size, located ~6.19-in. on center from the spatula paddle end, and slightly less than 1" from the head end, which places it between the raised support ribs of the shaft. Its location facilitates the user's placing the tip of the brush into the opening while the dog bone end is immersed in liquid preservative. The hole does not impact the way the spatula is used to sample the ectocervix.

- **New technological characteristic**
  The hole in the exCellerator™ can be considered a new technological characteristic. Its use **minimizes inter-operator variability** among collectors in removing the cytological sample from the endocervical brush. It does not affect how either the spatula or endocervical brush are used to remove cells from the ectocervix and endocervix, how cells are transferred from either device into liquid preservative, or how and what testing is performed on the sample.

Testing - Biocompatibility:
Biocompatibility tests were conducted to ensure safety and effectiveness of the device:

Summary Table: Biocompatibility Assessments

Assessment	Test	Criteria	Result
Cytotoxicity	MEM Elution Cytotoxicity Assay (ISO)	Non-Cytotoxic	Passed
Irritation	Vaginal Mucosal Irritation Test (ISO)	Non-Irritant	Passed
Sensitivity	Guinea Pig Maximization Test (ISO)	Non-sensitizer	Passed

Testing – Performance – Non-Clinical:
Mechanical tests were conducted to demonstrate substantial equivalence of the device to the predicate in terms of safety and effectiveness.

Summary Table: **Structural Assessments**

Assessment	Test Performed	Acceptance Criteria	Control Mode		Group	Result
Static Bend	Static Cantilever Bend	< 2-3mm	Displacement (Bend)	Load	A	**Passed**
					B	**Passed**
Static Tension	Static Tension	< 1mm	Deformation	Force	A	**Passed**
					B	**Passed**
Static Torsion	Static Torsion	< 45°	Angular Displacement	Torque	A	**Passed**
					B	**Passed**

*Production Lots: Group A – 2017, Group B – 2009 Shelf Life Successfully Assessed to be > 7 years

Testing – Dimensional Measures

Dimensional Assessments were made to ensure production consistency of the device.

Summary Table: **Dimensional Assessments**

Measurement (inches)	Acceptance Criteria	Result
Length	< .0050 Std Dev	**Compliant**
Width - Rail	< .0050 Std Dev	**Compliant**
Width – Paddle End	< .0050 Std Dev	**Compliant**
Width – Head End	< .0050 Std Dev	**Compliant**
Height - Rail	< .0050 Std Dev	**Compliant**
Height – Paddle End	< .0050 Std Dev	**Compliant**
Height – Head End	< .0050 Std Dev	**Compliant**
Hole Length	< .0050 Std Dev	**Compliant**
Hole Width	< .0050 Std Dev	**Compliant**
Hole to Proximal End	< .0050 Std Dev	**Compliant**
Hole to Distal End	< .0050 Std Dev	**Compliant**

Performance Data – Bench:

Bench testing and data analysis were performed to demonstrate substantial equivalence of the ExCellerator spatula to the predicate in terms of safety and effectiveness.

- **RWE Data:** RWE data was presented and demonstrated comparably equivalent or improved adequacy and diagnostics when using the ExCellerator spatula as both primary and complementary (secondary) device to collect and transfer cervical samples into the ThinPrep vial when compared with the standard spatula.

- **Validation Data**: Validation data was presented to demonstrate safety and effectiveness of the ExCellerator device when used as collecting device and as an aid in transferring sample from the IVD labeled cytobrush into ThinPrep PreservCyt Vial.

Substantial Equivalence Discussion

The ExCellerator™ cervical cytological spatula is processed by manufacturing methods and materials that are similar to those used for manufacturing of the predicate device: Medscand® Pap-Perfect Plastic Spatula. The Medscand® Pap-Perfect Plastic Spatula is the approved and distributed device within the ThinPrep Pap Test System.

ExCellerator Testing and Validation Conclusion: The ExCellerator cervical spatula has met or exceeded validation criteria for all the tests performed and is considered substantially equivalent to the predicate device.

New device:	ExCellerator™ cervical cytological spatula
Predicate device:	Spatula, cervical, cytological
Trade name:	Pap Perfect Plastic Spatula
Model number:	Cooper Surgical Item #11080
510(k) submitter/holder:	International Cytobrush, Inc.
510(k) number:	K861389

Intended Use: Primary Use: Same as the predicate device: For collecting ectocervical cytological material. Secondary Use: As aid in achieving a more complete transfer of cytological material from the endocervical brush (cytobrush) into the PreservCyt Vial for Pap smear testing.

Comparison with Predicate Device

Item	Candidate Device	Predicate
Device Name	ExCellerator Cervical Spatula	Pap Perfect Spatula
510(k) Number	K182049	K861389
Product Code	HHT	Same
Intended Use	The ExCellerator™ Cervical Collection Device is a cervical spatula intended for collecting ectocervical specimens for the ThinPrep Pap test. The device is also intended to be used to aid in a more complete transfer of the specimen material from the endocervical brush (cytobrush), to the PreservCyt solution for ThinPrep Pap testing. The ExCellerator™ device must be used with an IVD labeled endocervical brush. The collected specimen is transferred from the exCellerator™ device and endocervical brush	Same Secondary Feature Not Applicable

	into ThinPrep vial in accordance with the specified procedure. 'Caution: For use by medical professionals only'	
Material	Plastic	Same
KeyDimensions	Overall Length: ~7.13"	Same
	Paddle End Width: ~.50"	Same
	Head End Width: ~.70"	Same
Supplied	Non-Sterile - Disposable	Same

- **New technological characteristics**

  The hole in the exCellerator™ can be considered a new technological characteristic. Its use **minimizes inter-operator variability** among collectors when removing the cytological sample from the endocervical brush. It does not affect how either the spatula or endocervical brush are used to remove cells from the ectocervix and endocervix, how cells are transferred from either device into the liquid preservative, or how and what testing is performed on the sample.

Substantial Equivalence Decision

The subject and predicate devices have similar intended use and technological characteristics. Dimensions and material are the same. Biocompatibility testing, Mechanical testing and Performance data- Bench (Rear World Evidence data and Validation data), all met the pre-specified study acceptance criteria and demonstrated safety and effectiveness of the ExCellerator Cervical Collection Device. The subject device is substantially equivalent to the predicate device.