DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2017

KOLPLAST CI SA
c/o Yolanda Smith
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K153128
Trade/Device Name: Kolplast Cervical Sample Collection Kit
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HHT
Dated: December 27, 2016
Received: December 27, 2016

Dear Ms. Smith:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Kolplast Cervical Sample Collection Kit

Indications for Use *(Describe)*
The Kolplast Cervical Sample Collection Kit is intended for collection of cytological specimens from the ectocervix and the endocervix for conventional Pap Smear Test or Liquid-Based ThinPrep® Pap Test with PreservCyt® solution.

For prescription use only.

It is not intended for use in pregnant women and should be used by a clinical or other qualified health professional only.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
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

510(k) Owner:

KOLPLAST CI SA
Estrada Municipal IVA 136. No. 418 Barrio da Mina
Itupeva - SP
Brazil 13295-000
(Tel): +55 11 4961 0972 / +55 11 4961 0920
(Fax): +55 11 4961 0930

Contact Person: Daniela Feracin
Preparation Date: December 21, 2016

Device Information:

Trade Name:	Kolplast Cervical Sample Collection Kit
Common/Usual Name:	Cervical Collection Kit
Classification Name:	Obstetric-Gynecologic Specialized Manual Instrument
Regulation Number**:**	21 CFR 884.4530
Product Code:	HHT
Device Class:	Class II

Predicate Devices:

Pap Smear Kit (K861389)

Device Description:

The Kolplast Cervical Sample Collection Kit is composed of the Kolplast Cervical Brush Protected Tip and the Kolplast Cervical Plastic Spatula and is a single use, non-sterile, disposable manual gynecological device. The Cervical Brush Protected Tip is intended for the collection of cytological specimens from the endocervix and the Cervical Plastic Spatula is intended for the collection of cytological specimens from the ectocervix. The Cervical Brush Protected Tip has a head consisting of white nylon bristles, and secured by stainless steel to the plastic handle. During collection of endocervical cells, the Cervical Brush Protected Tip is inserted into the cervix, rotated once via the handle and removed from the cervix. The collected cytological specimen is then transferred to the glass slide by smearing, or to the preservative fluid in a container by rotating the tip 10 times while pushing against the container wall. The Kolplast Plastic Spatula is made of plastic and incorporates a long edge and a notched end. During

collection of ectocervical cells, the notched end is put against and rotated 360° around the circumference of the ectocervix. The retained cytological specimen is then transferred to the same glass slide by smearing, or to the preservative fluid in the same container by swirling 10 times. The collected samples on glass slide, or in preservative fluid in a container will be sent to a cytology lab for Pap Test analysis.

Indications for Use:

The Kolplast Cervical Sample Collection Kit is intended for collection of cytological specimens from the ectocervix and the endocervix for conventional Pap Smear Test or Liquid-Based ThinPrep® Pap Test with PreservCyt® solution.

For prescription use only.

It is not intended for use in pregnant women and should be used by a clinical or other qualified health professional only.

Comparison with Predicate Device:

Item	Proposed Device	Predicate Device
Device name	Kolplast Cervical Sample Collection Kit	Pap Smear Kit
510(k) number	K153128	K861389
Product Code	HHT	Same
Reguation No.	21 CFR §884.4530	Same
Intended Use	The Kolplast Cervical Sample Collection Kit is intended for collection of cytological specimens from the ectocervix and the endocervix for conventional Pap Smear Test or Liquid-Based ThinPrep® Pap Test with PreservCyt® solution. For prescription use only. It is not intended for use in pregnant women and should be used by a clinical or other qualified health professional only.	For collection and transportation of gynecological smears used in Papanicolaou's Exfolative Cytology Test.

Item	Proposed Device	Predicate Device
Device components	Brush and spatula	Brush and spatula
Composition	Brush: Plastic handle and a head with woven nylon interlaced in a stainless steel twisted wire; Spatula: plastic.	Same
Material	Brush head: Nylon and stainless steel 304; Brush handle: plastic; Spatula: plastic.	Same
Dimensions	Brush Head length: 0.08 inches Head diameter: 0.27-0.19 inches Overall length: 7.2 inches. Spatula Overall length: 7.2 inches Concave edge length: 0.82 inches.	Brush Head length: 0.09 inches Head diameter: 0.27-0.19 inches Overall length: 7.7 inches. Spatula Overall length: 7.2 inches Concave edge length: 0.82 inches.
Supplied	Non-sterile, disposable	Same

Non-Clinical Tests Performed:

The following biocompatibility tests were conducted on this device to ensure safety:

- Cytotoxicity – MEM Elution (ISO 10993-5:2009)
- Sensitization – Guinea Pig Maximization (ISO 10993-10:2010)
- Irritation – Skin Irritation (ISO 10993-10:2010)

The following mechanical tests were conducted on this device to ensure performance:

- Tensile strength test evaluating break and displacement in cervical brush and spatula
- Decoupling rotation test evaluating the fixing resistance of the nylon bristles against rotation and shear force
- Shelf-life test - The shelf life of the subject device is 5 years. This is based on the results of real time aging studies that demonstrated that the device maintains its specifications over the duration of its shelf life

Clinical Tests Performed:

The following clinical tests were conducted on this device to ensure effectiveness:

- Collection of cervical specimens for conventional Pap Smear Method
- Collection of cervical specimens for Liquid-Based Pap Test Method

Substantial Equivalence Discussion

The subject and predicate devices have the same intended use and technological characteristics (design and material). They also have comparable dimensions. The minor differences in dimensions do not raise any concerns. The non-clinical tests and clinical tests were conducted to ensure safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.