

510(k) Summary

MAR 10 1997

Trade Name: EpiScreen™

Common Name: Oral Specimen Collection Device

14970357

Device Description

The EpiScreen device consists of a treated absorbent cotton fiber pad affixed to a nylon stick (Collection Pad) and a preservative solution in a plastic container (Specimen Vial). The Collection Pad is impregnated with a mixture of common salts and gelatin, creating a hypertonic environment which produces an osmotic gradient across the buccal and gingival mucosa. The pad is placed in contact with the gingival mucosa (between the lower gum and cheek) which enhances the flow of mucosal transudate onto the absorptive cotton fibers of the pad. Following the collection period, the Collection Pad is removed from the mouth and placed into a Specimen Vial. The vial contains a preservative solution which serves to inhibit the growth of oral microorganisms recovered on the Collection Pad. The vial is sealed with a plastic cap and transported to a laboratory for processing and testing.

Intended Use

EpiScreen is intended to collect oral fluid specimens, contain those specimens, and preserve the specimens after collection and during transport from the collection area to the laboratory.

Classification

EpiScreen is classified as, or is substantially equivalent to, one or more of the following:

- Specimen Container (Class I, 21 CFR §880.6175, General Hospital and Personal Use Devices, General Hospital Panel, Product Code 80FMH);
- Specimen Transport and Storage Container (Class I, 21 CFR §880.3250, Hematology and Pathology Devices, Pathology Panel, Product Code 88KDT);
- Absorbent Tipped Applicator (Class I, 21 CFR §880.6025, General Hospital and Personal Use Devices, General Hospital Panel, Product Code 80FOR);
- Microbiological Specimen Collection and Transport Device (Class I, 21 CFR §866.2900), Immunology and Microbiology Devices, Microbiology Panel, Product Code 83LIO).

Like EpiScreen, these devices are used for taking specimens, and for containing those specimens, and preserving (with or without a fixative solution) the viability and integrity of the specimens during transport from the collecting area to the laboratory.

Comparison of Technological Characteristics

EpiScreen is substantially equivalent to the following devices:

- Saliva Sampler manufactured by Saliva Diagnostics Systems of Vancouver, WA.
- Salivette manufactured by Sarstedt, Inc. of Newton, NC.
- Saliva Sac manufactured by BioQuant, Inc. of Ann Arbor, MI.

Like EpiScreen, the Saliva Sampler, Salivette, and Saliva Sac are intended for collecting an oral fluid specimen, and for containing and transporting that specimen. The following table lists the indications and components for EpiScreen and the three equivalent devices. Note that all four devices share the same indication as well as major components (collection apparatus and transport container). While EpiScreen has different technological characteristics than the predicate devices discussed here, EpiScreen does not raise different questions of safety and efficacy.

Comparison Table: EpiScreen, Saliva Sampler, Saliva Sac, and Salivette

	EpiScreen	Saliva Sampler	Saliva Sac	Salivette
Indication	Collection/ transport of oral fluid specimens			
Collection Apparatus	✓	✓	✓	✓
Transport Container	✓	✓	✓	✓
Fixative Solution	✓	✓	N/A	N/A
Suspension Insert	N/A	N/A	N/A	✓
Volume Indicator	N/A	✓	N/A	N/A



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

Epitope, Inc.
Caroline R. Sayre, RAC
Regulatory Affairs Supervisor
8505 SW CREEKSIDE PLACE
BEAVERTON, OREGON 97008

FEB 06 2015

Re: K970357
Trade/Device Name: EpiScreen™ Oral Specimen Collection Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: II
Product Code: PJD
Dated: January 29, 1997
Received: January 30, 1997

Dear Ms. Sayre:

This letter corrects our previous Substantially Equivalent (SE) letter of March 10, 1997.

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 regulation (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" (21CFR 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,


for : Courtney H. Lias, Ph.D.

Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: EpiScreen™ Oral Specimen Collection Device

Indications for Use:

EpiScreen is intended for use in the collection, preservation, and transport
of oral fluid specimens.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sharon Hansen

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K920357

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

3