



**EPITOPE**

**K973395**

8505 SW Creekside Place  
Beaverton, Oregon 97008  
503-641-6115  
fax: 503-643-2781

FEB 13 1998

## EpiScreen™ Oral Specimen Collection Device

### 510(k) Summary

[as required by 21 CFR 807.92(c)]

submitted by  
**EpiTope, Inc.**

8505 SW Creekside Place  
Beaverton, OR 97008  
phone: 503-641-6115  
fax: 503-643-2781

contact:  
Caroline Sayre  
Regulatory Affairs

August 19, 1997

## 510(k) Summary

**Trade Name:** EpiScreen™  
**Common Name:** Oral Specimen Collection Device

---

### 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 mucosae. 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

This 510(k) contains a modification to the package insert of the EpiScreen Oral Specimen Collection Device (510(k) #970357). This product has been deemed a Class II device under the following classification:

- Blood Specimen Collection Device (Class II, 21 CFR §862.1675, Clinical Chemistry and Clinical Toxicology Devices, Product Code 75JKA)

### Comparison of Technological Characteristics

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. Since there has been a modification only to the EpiScreen package insert and not the device itself, Epitope considers this device to be substantially equivalent to the originally cleared EpiScreen device.

### Comparison Table: Current EpiScreen vs. Modified EpiScreen

Feature	Current EpiScreen	Modified EpiScreen
Indication	Collection/transport of oral fluid specimens	Collection/transport of oral fluid specimens
Collection Apparatus	✓	✓
Transport Container	✓	✓
Preservative Solution	✓	✓

The EpiScreen device described in this 510(k) is identical to the currently cleared device and therefore does not raise new questions of safety and efficacy.



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: K973395  
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: August 19, 1997  
Received: August 21, 1997

Dear Ms. Sayre:

This letter corrects our previous Substantially Equivalent (SE) letter of February 13, 1998.

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): \_\_\_\_\_

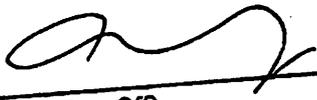
Device Name: EpiScreen™ Oral Specimen Collection Device

Indications for Use:

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

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number 129-73395

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

Indications for Use  
EpiScreen 510(k)

Labels on Laboratory

Statement