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K984361

OSBORN LABORATORIES
A ChoicePoint™ Company

510(k) SUMMARY

**Osborn Laboratories
Oral-Eze™ Oral Fluid Collection System**

December 4, 1998

Submitter Information:

Osborn Laboratories
19401 West 117th Street
Olathe, Kansas 66062

Submitter's Name: Gilbert P. Bourk III
Phone: (913) 390-7146

Device Name:

Osborn Laboratories Oral-Eze Oral Fluid Collection System

Common Name: Oral fluid collection kit

Classification Name: Blood specimen collection device

Predicate Device Equivalence:

Substantial equivalence is claimed to the Saliva-Sampler® Saliva Collection Device (primary predicate device), cleared for commercial distribution per K942435, and to the EpiScreen™ Oral Collection Device (secondary predicate device), cleared for commercial distribution per K973395 and K970357.

Device Description:

The Oral-Eze Oral Fluid Collection System is a device used by a person under the supervision of a trained health care professional to obtain an oral fluid specimen and have the specimen contained for transport to a laboratory. The device consists of the following:

- A collector pad holder/handle with a collector pad, contained in a sealed "peel-apart" plastic envelope. The collector pad holder/ handle itself consists of two parts, a collector pad holder and a collector pad slider. The collector pad is held in the holder/handle by a pin in the slider that fits into a hole in the collector pad, and by the holder, which keeps the pad from falling off the pin. The slider has a round indicator port in it. A blue color appears in this indicator port when a predetermined amount of oral fluid has been collected.
- An Oral Fluid Collection Tube with a screw-on lid, containing preservative fluid.
- A clear plastic sealed envelope that contains all three of the above items.

Intended Use:

The Oral-Eze Oral Fluid Collection System is a prescription device, intended for use by a person under the supervision of a trained health care professional to collect oral fluid specimens, contain these specimens, and preserve the specimens after collection and during transport from the collection area to the laboratory.

Comparison of Technological Characteristics:

Essentially, the Oral-Eze and Saliva•Sampler devices use the same basic technology, i.e., collecting an oral fluid specimen on a fibrous pad and preserving it in a buffer solution contained in a collection tube. One major difference is that with the Oral-Eze device the collector pad is placed in the buccal cavity, whereas with the Saliva•Sampler the collector pad is placed sublingually. Another major difference is that only the collector pad of the Oral-Eze device is contained in the collection tube, whereas both the handle and collector pad of the Saliva•Sampler predicate device are contained in collection tube. In addition, even though the Oral-Eze device is not sterile and the handle and collector pad of the Saliva•Sampler predicate device are sterile, the handle and collector pad of the secondary predicate device, the EpiScreen Oral Specimen Collection Device, are not sterile.

Summary of Performance Testing:

To assess the suitability of the Oral-Eze Oral Fluid Collection System, both the Oral-Eze device and the Saliva•Sampler predicate device were tested for a number of characteristics, such as specimen collection time and volume collected. The test results demonstrated that the Oral-Eze device is substantially equivalent to the Saliva•Sampler predicate device.

To obtain assurance that the oral fluid specimens would remain stable even after undergoing the extreme temperatures that can be experienced by any object sent by common carrier or by the U.S. Mail, Oral-Eze collection tubes with collector pads containing oral fluid specimens were subjected to environmental testing. The test results were considered to be within acceptable accuracy limits.

Conclusions:

Based on the above, we have concluded that the Oral-Eze Oral Fluid Collection System is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use.



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

Osborn Laboratories
Mr. Gilbert P. Bourk, III
Vice President and General Counsel
19401 WEST 117th ST.
OLATHE, KANSAS 66062

FEB 06 2015

Re: K984361
Trade/Device Name: Osborn Laboratories Oral-Eze™ Oral Fluid Collection System
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: II
Product Code: PJD
Dated: December 4, 1998
Received: December 7, 1998

Dear Mr. Bourk:

This letter corrects our previous Substantially Equivalent (SE) letter of January 13, 1999.

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): K984361

Device Name: _____

Indications For Use:

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Oral-Eze Oral Fluid Collection System

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The Oral-Eze Oral Fluid Collection System is a prescription device, intended for use by a person under the supervision of a trained health care professional to collect oral fluid specimens, contain these specimens, and preserve the specimens after collection and during transport from the collection area to the laboratory.

Sean Coogan
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984361

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)