510(k) summary as required by 21 CFR 807.92

SEP 13 2011

Camurus AB, episil® K101769

Submitter's name, address, telephone number, and contact person

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Date prepared

June 22, 2011

Name of device

Trade name: episil®
Common name: Wound dressing
Classification name: Unclassified

Predicate device

Gelclair Concentrated Oral Gel (K013056)

Intended use/Indications for use

episil® has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy).

Device Description

episil® is a medical device constituting an oromucosal liquid in a multidose container and is without active pharmaceutical ingredient. The oromucosal liquid transforms *in situ* to a bioadhesive oromucosal gel by uptake of small amounts of aqueous fluid. episil® has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including Oral Mucositis/ Stomatitis (may be caused by chemotherapy or radiotherapy). The oromucosal liquid is made of six ingredients including glycerol dioleate, soy phosphatidyl choline, ethanol, propylene glycol, polysorbate 80, and peppermint oil, which are all GRAS for the intended use.

Substantial Equivalence
episil® is as safe and effective as the Gelclair Concentrated Oral Gel (K013056). episil® has the same intended uses and similar indications for use, characteristics, and modes of action as the predicate device. The mode of action of episil® is achieved in the same manner as the identified predicate device (Gelclair Concentrated Oral Gel (K013056)) which is through the formation of a protective layer over the oral mucosa. episil® and Gelclair Concentrated Oral Gel are used by swirling in the mouth either directly or after mixing with water. Both are provided non-sterile.

The components of episil® have the same function as in the cited predicate device; with a mixture of film-forming excipients, flavors/sweeteners and ingredients required for manufacturing and viscosity.

episil® and the Gelclair Concentrated Oral Gel are both used on the oral mucosa and are both administered by swirling in the mouth. Episil® is recommended for use 2-3 times a day or as needed as is Gelclair Concentrated Oral Gel (K013056).

Performance data has been provided which demonstrates the minor differences between episil® and the predicate device raises no new issues of safety or effectiveness. Thus, episil® is substantially equivalent to the identified predicate device.

Performance Testing
Non-clinical and clinical performance testing was performed to support substantial equivalence claims. episil® conducted systemic toxicity testing in Syrian hamsters including oral irritation testing.

A randomized, repeat dose study of episil® in bone marrow transplant patients suffering from oral mucositis, was performed where episil® was given three times daily during 7 days together with cryotherapy compared against cryotherapy alone. The study showed that patients receiving episil® had less pain and required significantly less pain medication and parenteral nutrition than the control group.

The results show a significant reduction of oral pain which is similar to the reduction of pain reported in the literature for the predicate device Gelclair® (Lindsay et al. (2009), Australian Nursing Journal, 16 (9), 30). Therefore, Camurus has determined that episil® is safe and effective for its intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Camurus AB
C/O Ms. Maureen O'Connell
Regulatory Consultant
Premier Research Group, Limited
5 Timber Lane
North Reading, Massachusetts 01864

SEP 13 2011

Re: K101769
Trade/Device Name: Episil®
Regulation Number: Unclassified
Regulation Name: Dressing, Wound and Burn, Hydrogel with Drug and /or Biologic
Regulatory Class: Unclassified
Product Code: MGQ
Dated: August 15, 2011
Received: August 16, 2011

Dear Ms. O'Connell:

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 Part 801); 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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CAMURUS

Date: June 18, 2010

Indications for use statement

510(k) Number (if known): K101769

Device Name: Episil®

Indications for Use:

Episil® has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy).

Prescription Use___X__ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101769