K131396

510(k) SUMMARY

I. ADMINISTRATIVE

Submitter:
Elba Laboratories, Inc.
1925 West Maple Road
Troy, MI 48084
(248) 288-6098

SEP 30 2013

Contact Person: Michael Froehlich

Date of Preparation: September 25, 2013

II. DEVICE NAME

Proprietary Name: Wired Mouth Protector (WMP)

Common Name: Wired Mouth Protector

Classification Name: Wax, Dental, Intraoral; 21 CFR §872.6890

III. PREDICATE DEVICE

Brace Eze; K020009 ; Udent, Inc.

IV. DEVICE DESCRIPTION

The Wired Mouth Protector consists of a non-sterile strip of non-latex foam with a slit in the middle that is inserted into the front of the mouth between the teeth and lip area with the slit in the center to provide a soft barrier to help protect the oral mucosa from contact with wired mouth hardware. It is changed three times daily or more often if needed.

Biocompatibility testing of the device has been conducted. The device was shown to be non-cytotoxic in the agar diffusion test as well as the MEM elution test using L929 mamalian cells. Primary skin irritation testing in rabbits showed that the device is not considered to be a

primary skin irritant (Primary Dermal Irritation Index=0.0). Ocular irritation testing in rabbit eyes showed that the device is not an ocular irritant. An acute oral toxicity study in mice showed that extracts were not considered toxic at an oral dose of 40 mL/kg body weight; the LD_{50} was > 40 mL/kg b.w.

V. INTENDED USE

Provides a soft barrier between wired mouth hardware and oral mucosa to help relieve discomfort for convalescing oral and maxillofacial surgery patients.

VI. COMPARISON TO PREDICATE DEVICE

The Wired Mouth Protector provides a similar function as the predicate device; i.e., protecting oral mucosal tissue from discomfort and damage. The composition of the Wired Mouth Protector differs from that of the predicate (foam vs. gel); however, the safety of the foam material for oral use has been well established in standard biocompatibility testing.

VII. CONCLUSION

Based on design considerations and the results of biocompatibility testing, we conclude that, in terms of protective function, the Wired Mouth Protector performs at least as well as the predicate device. The Wired Mouth Protector is therefore considered to be substantially equivalent to the above-mentioned predicate device.

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

September 30, 2013

Elba Laboratories, Incorporated
C/O Mr. Richard A. Hamer
Vice President/Regulatory Affairs
Ferndale Pharma Group, Incorporated
780 West 8 Mile Road
FERNDALE MI 48220

Re: K131396
Trade/Device Name: Wired Mouth Protector
Regulation Number: 21 CFR 872.6890
Regulation Name: Intraoral Dental Wax
Regulatory Class: I
Product Code: PFL
Dated: July 9, 2013
Received: July 12, 2013

Dear Mr. Hamer:

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 contact 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. 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K131396

Device Name: Wired Mouth Protector

Indications for Use:

Provides a soft barrier between wired mouth hardware and oral mucosa to help relieve discomfort for convalescing oral and maxillofacial surgery patients.

Prescription Use _____ OR Over-the Counter Use __X____
(Per 21 CFR §801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joel M. Anderson
2013.09.30
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