APR 2 7 2005

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K050188

510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	MedicSense, Ltd. Galdani Bldg 58b Amal St. Kiriat Arie, Petach Tikya, Israel www.medicsense.com
1. (b)	***Manufacturer Address:***	EpiSafe Medical Devices, Ltd. 84 Yitzhak Rabin Rd. Givataym, Israel 53483 972-3-571-0768
	Mfg. Phone:	Eran Lavi, CEO
	Contact Person:	January 19, 2005
	Date:	
2.	***Device & Classification Name:***	Bite Block, Class 2, Product Code 84JXL, 21 CFR 882.5070 EpiGuard
3.	***Predicate Devices:***	Ventil-A Bite Block K992269 MouthGuard Bite Block K864181 Sage Bite Block Pre-Amendment
4.	***Description:***	The EpiGuard is a single use oral protective device manufactured from biocompatible silicone. It is provided clean (non-sterile). Besides providing a physical barrier to prevent tongue and cheek damage of the user, the device will maintain an open airway in the mouth cavity and allow the free flow of air and vomit. In addition, the device is griped under the palatals and teeth of the user while also being held in front by the interior surface of the lips. This allows the EpiGuard to be fixed to the necessary position to prevent it from being swallowed.
5.	***Intended Use:***	The EpiGuard is intended for the prevention of oral soft tissue damage during epileptic tonic-clonic seizures proceeded by an aura.
6. (a)	***Comparison of Technological Characteristics:***	With respect to technology, the EpiGuard is substantially equivalent to its predicate devices of being a bite block in terms of design principles. Its dimensions were based upon the measurements from dental impressions of men and women above the age of 10. The biocompatible material has the necessary tensile strength properties to prevent degradation when utilized.
6. (b)	***Clinical Testing:***	An observational study was conducted on 10 subjects with 3 devices (30 trials total) to evaluate 13 specific aspects of the EpiGuard. The subjects graded the performance of the device on a scale of 1-5. The outcome of this study did not indicate any objectionable performance of the device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2005

EpiSafe Medical Devices, LTD.
C/o Mr. George J. Hattub, RAC & CQE
Senior Staff Consultant
MedicSense, Ltd.
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K050188
Trade/Device Name: EpiGuard
Regulation Number: 21 CFR 882.5070
Regulation Name: Bite block
Regulatory Class: II
Product Code: JXL
Dated: April 13, 2005
Received: April 15, 2005

Dear Mr. Hattub:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050188

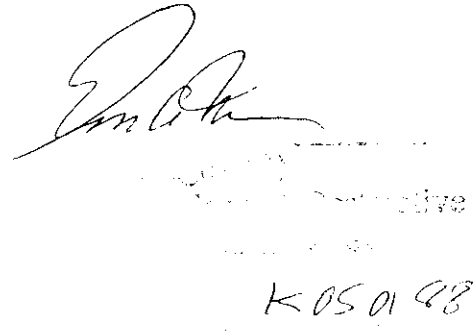
Device Name: EpiGuard

Indications For Use: The EpiGuard is intended for the prevention of oral soft tissue damage during epileptic tonic-clonic seizures proceeded by an aura.

Prescription Use X AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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