K013696

NOV 2 8 2001

Pre-market Notification
510(k) Summary of Safety and Effectiveness Information

MANUFACTURER
Silmed Incorporated
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Millville, UT 84326
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MANUFACTURER CONTACT PERSON
Mr. Rama Gundlapalli
Vice President and Chief Technology Office

PROPRIETARY NAME
Silmed Nasal Septal Button

COMMON NAMES
Button, Nasal Septum
Nasal Septal Button

CLASSIFICATION NAME
Button, Nasal Septum

CLASSIFICATION REFERENCE
Currently, no FDA classification exists for the Button, Nasal Septum

DEVICE PRODUCT CODE
77 LFB

CLASSIFICATION PANEL
Ear, Nose and Throat Devices

PROPOSED REGULATORY CLASS
In accordance with FDA classification of Button, Nasal Septal as Class II medical devices, this device system is proposed for placement in Class II.

REASON FOR PREMARKET NOTIFICATION
The Silmed Nasal Septal Button is a new medical device proposed for placement in Class II.

SPECIAL CONTROLS
At this time, Food and Drug Administration generated Performance Standards applicable to Silmed Nasal Septal Button are not in force. However, Silmed, Inc. has looked at comparative configurations to demonstrate the substantial equivalence of the device. Additionally, Silmed, Inc. utilizes materials and vendor certifications, in-house standard operating procedures (SOP's) and ASTM standards, as appropriate.

INDICATIONS FOR USE
Silmed Nasal Septal Button is indicated for use for non-surgical closure of nasal septum perforations.

SUBSTANTIALLY EQUIVALENT PREDICATE DEVICES

Silmed, Inc. believes that several commercially available devices are substantially equivalent to the Silmed Nasal Septal Button. Within the proposed class, the following devices are used as predicate devices for comparison.

1. Nasal Septal Button
   Boston Medical Products, Inc., West Borough, MA
2. Micromedics Inc., Nasal Septal Button
   Micromedics, Inc., Eagan, MN
3. Hood Nasal Septal Button
   Hood Laboratories Inc., Pembroke, MA

DEVICE DESCRIPTION

Silmed, Inc. Nasal Septal Button is indicated for use for non-surgical closure of nasal perforations. The Silmed Nasal Septal Button is designed in three sizes: small, medium and large.

The Silmed Nasal Septal Button features two circular flanges centrally connected by a post. The circular flanges come in varying diameters depending on the size of the button. The central post is elliptical in shape. The post acts as a bridge between the two flanges. The post feature may also be explained as an elongated circular section.

The post dimensions vary with size and with the circular flange diameter based on the size of the nasal septal button. The device is manufactured using soft medical grade silicone and can be trimmed at the time of placement.

SUBSTATINTIAL EQUIVALENCE COMPARISION

Based on the design concept, indications for use, use of standard materials, feature comparisons to selected predicate devices, Silmed Inc. believes that sufficient evidence exists to conclude that the Silmed Nasal Septal Button is substantially equivalent to existing legally marketed nasal sepal buttons.

To begin, the materials, method of manufacture, methods of cleaning and device packaging for all the Silmed Nasal Septal Button components are equivalent to those used for the predicate devices.

The Silmed Nasal Septal Buttons are indicated for use for non-surgical closure of nasal perforations. The previously listed predicate device systems are similarly indicated for procedures involving septal perforations.

CONCLUSION

Based on the design concept, indications for use, use of standard materials and feature comparisons to the selected predicate devices, Silmed, Inc. believes that sufficient evidence exists to conclude that the Silmed Nasal Septal Button is substantially equivalent to existing legally marketed nasal septal buttons.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Silmed, Inc.
c/o Rama Gundlapalli
Vice President and Chief Technology Officer
87 West 300 South
Millville, UT 84326

Re: K013696
Trade/Device Name: Silmed Nasal Septal Button
Regulatory Class: Unclassified
Product Code: LFB
Dated: October 31, 2001
Received: November 7, 2001

Dear: Mr. Gundlapalli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEVICE INDICATION FOR USE

INDICATIONS FOR USE

Silmed Nasal Septal Button is indicated for use for non-surgical closure of nasal septum perforations.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K013696

Prescription Use Yes
(Per 21 CFR 801.109)