K980221

Silimed, L.L.C. **14014 Sullyfield Circle Suite C** **Chantilly, Virginia 20151**

SMDA SUMMARY

APR - 2 1998

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 .CFR 807.92.

Description: The *Silimed Nasal Retainer* was designed for prophylaxis of stenosis and cicatricial structures. It is recommended for all age groups, and for any type of nose. It has a functional format and can be sectioned by adjusting the length according to the requirement.

The *Silimed Nasal Retainer* is composed of chemically and mechanically resistance silicone elastomer (HCRA 35M). The elastomer is soft, smooth of surface and contains a defined volume of elastomer whose shape, density and overall consistency have been chosen to replace human tissue. It has a defined length, width and circumference for the two channels that form the opening for the right and left nostril.

The advantages of the Silimed Nasal Retainer are: 1) maintains the septum in a vertical position, 2) allows for nasal breathing immediately after the operation, without blocking air flow, 3) painless and non-traumatic, 4) easy to keep clean and 5) single patient use.

The *Silimed Nasal Retainer* is available in 13 sizes .

Silimed's Nasal Retainer is sterilized by ethylene oxide. The method of sterilization is shown on the package, which is a double peel pouch. An individual confirmation of each batch is carried out, as well as a quarterly confirmation by an independent laboratory.

Indications for Use: The *Silimed Nasal Retainer* is designed for use after aesthetic and reconstructive rhinoplasty, after rhinoseptoplasty, after rhinoseptocheiloplasty and/or primary and secondary rhinocheiloplasty (cleft-lip nose patients).

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Predicate Device:

Company	***Product***	***510(k)Number***
Boston Medical Products	Doyle Combo Nasal Airway Splint	K972151
Boston Medical Products	Bivalve Nasal Splint	K972096

Submitted by: _____
E.J.Smith, Consultant

Date: _____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Silimed, LLC
E.J. Smith
Consultant
c/o Smith Associates
P.O. Box 4341
Crofton, MD 21114

Re: K980221
Silimed Nasal Retainer
Dated: January 22, 1998
Received: January 22, 1998
Regulatory class: Unclassified
Procode: 77 LYA

APR - 2 1998

Dear Mr. Smith:

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 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980221

Device Name: Silimed Nasal Retainer

Classification Panel: LYA

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-the-Counter Use** _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980221