Section 7.0 510(k) Summary

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Genzyme Corporation is providing a summary of the safety and effectiveness information available for Hylasine™.

7.1 Sponsor/Applicant Name and Address

Genzyme Corporation
One Kendall Square
Cambridge, MA. 02139

7.2 Sponsor Contact Name

Alexander E. Kuta, Vice President, Regulatory Affairs
Phone: 617/374-7358, Fax: 617/374/7470, e-mail: alex.kuta@genzyme.com

7.3 Date that 510(k) Summary Was Prepared

June 26, 2001

7.4 Name of the Medical Device

Classification name:	Intranasal Splint (Ear, Nose & Throat)
Common/usual name:	Intranasal Splint
Proprietary name:	Hylasine™

7.5 Legally Marketed Devices to Which Substantial Equivalence is Claimed

Xomed MeroGel™ Nasal Dressing and Sinus Stent (Xomed, K982731)
Custom Nasal Splint (Boston Medical, K972082)
LactoSorb Ethmoid Stent (Walter Lorenz Surgical, K002131)

7.6 Description of the Device

HylaSine™, hylan B gel is a sterile, transparent, viscoelastic gel composed of cross-linked polymers of hyaluronan. This hyaluranon is a bioresorbable material that functions to fill nasal/sinus cavities following surgery or trauma and to keep mucosal surfaces separate during the healing process. During this time, the tamponade effect helps control minimal bleeding normally associated with routine sinus surgery. HylaSine leaves the site of placement by natural elimination, or it may be aspirated from the cavity earlier at the discretion of the physician.

7.7 Intended Use of the Device

HylaSine is indicated for use in patients undergoing nasal/sinus surgery as a space-occupying gel stent to separate and prevent adhesions between mucosal surfaces in the nasal cavity, to help control minimal bleeding following surgery or nasal trauma, and to prevent lateralization of the middle turbinate during the postoperative period.

7.8 Technological Comparison between Subject and Predicate Devices

Boston Medical Products' Custom Nasal Splint and Lorenz Surgical's LactoSorb Ethmoid Stent have similar indications as the proposed Hylasine. Boston Medical Products' Custom Nasal Splint prevents adhesions between mucosal tissues after surgery.

Xomed's MeroGel Nasal Dressing and Hylasine share a similar material composition in that they are both composed of derivatives of hyaluronic acid. Although Merogel has been cleared as an Epistaxis Balloon, it is used in the nasal/sinus cavity, as is an Intranasal Splint. Whether a hyaluronic acid product is classified as an Intranasal Splint or Epistaxis Balloon does not raise any new safety issues. Hylasine™ is also similar to Xomed's MeroGel Nasal Dressing and LactoSorb's LactoSorb Ethmoid Stent in that all three devices are bioresorbable.

Hylasine™, Boston Medical Products' Custom Nasal Splint and LactoSorb's LactoSorb Ethmoid Stent are all classified by the same product code of 77LYA with the generic name of Intranasal Splint

In conclusion, Hylasine™ has similar intended use, material composition, bioresorbability, and product code as other legally marketed devices.

Figure 7- 1Comparison to Marketed Devices

	Hylasine™ **Genzyme Corporation** **PROPOSED**	**MeroGel Nasal Dressing** **Xomed** **(K982731)**	**Custom Nasal Splint** **Boston Medical Products** **(K972082)**	**LactoSorb Ethmoid Stent** **Walter Lorenz Surgical** **(K002131)**
Device Name	Intranasal Splint	Epistaxis balloon	Intranasal Splint	Intranasal Splint
Product Code	77LYA	77EMX	77LYA	77LYA
Indications/Intended Use	For use in patients undergoing nasal/sinus surgery as a space-occupying gel stent to separate and prevent adhesions between mucosal surfaces in the nasal cavity, to help control minimal bleeding following surgery or nasal trauma, and to prevent lateralization of the middle turbinate during the postoperative period.	For use in the nasal/sinus cavities as a space-occupying dressing and/or stent, to separate mucosal surfaces and to help control minimal bleeding following surgery.	To provide septal support and reduce or prevent adhesions between the septum and lateral nasal wall following surgery	For use during ethmoidectomy procedures. The LactoSorb Ethmoid Stent is intended to keep the middle turbinate away from the lateral nasal wall during the healing process after nasal/sinus surgery. The stent provides enough rigidity in the nasal cavity to keep the middle turbinate from adhering to the lateral nasal wall.
Material Composition	Derivative hyaluronic acid	Derivative hyaluronic acid	Plastic	LactoSorb 82% PLLA/18% PGA
Bioresorbable	YES	YES	NO	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2001

Ms. Nancy A. Immel
Senior Regulatory Associate
Genzyme Corporation
1125 Pleasant View Terrace
Ridgefield, New Jersey 07657

Re: K012532
Trade Name: Hylasine™ Hylan B Gel
Regulation Number: 21 CFR 874.4780
Regulatory Class: Class I
Product Code: LYA
Dated: August 2, 2001
Received: August 6, 2001

Dear Ms. Immel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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

Section 2.0 Statement of Intended Use

HylaSine is indicated for use in patients undergoing nasal/sinus surgery as a space-occupying gel stent to separate and prevent adhesions between mucosal surfaces in the nasal cavity, to help control minimal bleeding following surgery or nasal trauma, and to prevent lateralization of the middle turbinate during the postoperative period.

Prescription Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012532