JAN 25 1999

LES LABORATOIRES BROTHIER S.A.

K984069

510(k) SUMMARY

ENTaxis™ Nasal Packing
(77 EMX)

1. SUBMITTER'S NAME
2. CONTACT PERSON AT LABORATOIRES BROTHIER
3. DATE THAT 510(k) SUMMARY WAS PREPARED
4. NAME OF THE MEDICAL DEVICE (Classification / Common / Proprietary)
5. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
6. DESCRIPTION OF THE DEVICE
7. INTENDED USE OF THE DEVICE
8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES
9. SUMMARY OF PRECLINICAL SAFETY STUDIES AND CONCLUSIONS FROM PRECLINICAL SAFETY STUDIES
10. SUMMARY OF PRECLINICAL PERFORMANCE STUDIES
11. CLINICAL SAFETY AND EFFICACY STUDY

1. SUBMITTER'S NAME

LABORATOIRES BROTHIER S.A.
41 rue de Neuilly
92000 Paris-Nanterre
FRANCE

Tel: 011-33-1-47 24 27 34
Fax: 011-33-1 47 25 51 58

2. U.S. REGULATORY CONTACT PERSON FOR LABORATOIRES BROTHIER S.A.

Evan Dick, Ph.D.
E.G. Dick & Associates
7527 Westmoreland Avenue
St. Louis, MO 63105

Tel: (314) 721-0112
Fax: (314) 721-7591

3. DATE THAT 510(k) SUMMARY WAS PREPARED
November 13, 1998

4. NAME OF THE MEDICAL DEVICE	
Classification name	*Balloon, epistaxis (nasal)* (Ear, Nose & Throat 77 EMX)
Common / usual name	*Nasal Packing*
Proprietary name	*ENTaxis™ Nasal Packing*

5. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
Algoderm Alginate Wound Dressing (Laboratoires Brothier, K905314) *Algosteril Alginate Dressing (Laboratoires Brothier, K922540)* *Nu Gauze Plain Packing Strip (Johnson & Johnson, K821150)* *Curity Petrolatum Gauze (Kendall, K973511)* *Merocel Nasal Packing (Merocel, K920394)*

6. DESCRIPTION OF THE DEVICE
ENTaxis™ Nasal Packings are highly conformable, sterile, hemostatic packings designed for managing bleeding in the nasal cavity and as post operative packings. ENTaxis™ nasal packings are 12" (30cm, 2g) "ropes" that are 100% composed of pure calcium alginate fibers.

7. INTENDED USE OF THE DEVICE

ENTaxis™ Nasal Packings are intended for nasal epistaxis and as post operative nasal packings.

8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES

ENTaxis™ Nasal Packings are highly conformable, sterile, hemostatic packings. The packings are 12" (30cm) long, 2 gm "ropes", similar in dimensions to predicate gauze strip packings such as Nu Gauze Plain Packing Strip (K821150) and Curity Petrolatum Gauze (K973511). ENTaxis and these predicate devices are composed of chemically similar natural fibers.

ENTaxis™ nasal packings are physically and chemically identical to Laboratoires Brothier calcium alginate wound dressing products that have been in U.S. interstate commerce since 1990 and that were reviewed under:

- *Algoderm Alginate Wound Dressing* (Laboratoires Brothier, K905314), and
- *Algosteril Alginate Dressing* (Laboratoires Brothier, K922540).

ENTaxis™ nasal packings and the identified predicate devices all act to help control nasal bleeding.

9. SUMMARY OF PRECLINICAL SAFETY STUDIES AND CONCLUSIONS FROM PRECLINICAL SAFETY STUDIES

ENTaxis™ Nasal Packing has been evaluated (under the brand name ENTaxis or Algosteril) though *in vitro* tests and animal safety studies. All of these results are consistent in indicating that this product is safe for use as a nasal packing.

Preclinical safety tests and the conclusions drawn for the test articles:

- Cytotoxicity: USP Elution Method
  - ▷ product *met the requirements of the USP.*
- Cytotoxicity: USP Agar Diffusion Test
  - ▷ product *met the requirements of the USP.*
- Cytotoxicity: Hemolysis Test
  - ▷ product *was found to be nonhemolytic.*
- Sensitization: Beuhler Method
  - ▷ product *was found to be a non-sensitizer.*
- Sensitization: Magnusson and Kligman Method
  - ▷ product *was found to be a non-sensitizer.*
- Primary Skin Irritation (24 Hour)
  - ▷ product *was found to be neither a dermal irritant nor a dermal corrosive.*
- Primary Skin Irritation (5 Day)
  - ▷ product *passed the skin irritation test in the rabbit.*
- Intranasal Irritation (3 Day Repeated Dose)
  - ▷ product *was found to be a non-irritant to the nasal mucosa and to produce no microscopic changes in the nasal tissues of rats.*
- Eye Irritation (3 Day Repeated Dose)
  - ▷ product *was found to be a non-irritant in rabbit eyes.*
- Intracutaneous Reactivity
  - ▷ product *complies with British Standard 5736-Part 4.*
- Acute Systemic Toxicity
  - ▷ product *passed i.v. and i.p. systemic injection tests in mice.*
- Repeated Dose Systemic Toxicity (7 Days)
  - ▷ product *was found to be non-toxic in mice with daily systemic dosing for seven days.*
- Microbiology: Effect On TSS-Associated *Staphylococcus aureus*
  - ▷ product *did not enhance the growth of TSS-associated S. aureus.*
- Rabbit Pyrogen Test
  - ▷ product *was found to be nonpyrogenic.*

10. SUMMARY OF PRECLINICAL PERFORMANCE STUDIES

The hemostatic efficay of Algosteril / ENTaxis (different brand names for an identical product) was evaluated *in vitro* and *in vivo*.

- *IN VITRO ASSESSMENT OF HEMOSTATIC EFFICACY*

Hemostatic Capacity Study of Algosteril Compared to Three Reference Test Articles. Biomatech S.A. Study No. 288E702. February 19, 1998.

- ▷ *Algosteril / ENTaxis is hemostatic.*
- ▷ *Hemostatic effects, in vitro, are equal to or greater than those of oxidized cellulose.*

- *IN VIVO ASSESSMENT OF HEMOSTATIC EFFICACY*

Short-Term Study In Pigs of A Calcium Alginate (Algosteril): Assessment of Primary Hemostatic Efficacy. Biomatech S.A. Study No. 288E701 November 7, 1997.

- ▷ *Product is hemostatic on actively bleeding surgical wounds.*
- ▷ *Hemostatic potency (both dry and wet) was equal to or greater than the hemostatic potency of oxidized cellulose.*
- ▷ *The hemostatic potency of Algosteril/ENTaxis calcium alginate is greater when moistened with saline than when dry*
- ▷ *Algosteril / ENTaxis, when moistened with saline, releases more easily from a wound bed than either oxidized cellulose or dry calcium alginate.*

11. CLINICAL SAFETY AND EFFICACY STUDY

ENTaxis™ Nasal Packing has been clinically evaluated as a hemostatic, post operative nasal packing in ENT sinus surgery. Results indicate that this product is safe and effective for this use.

R. Peynegre, P. Bonfils, L. Castillo, *et al.* 1998. *Clinical Assessment of Efficacy and Safety of Two Nasal Packings, a Calcium Alginate (ENTaxis™) and Polyvinyl Acetal (Merocel™) in Bilateral ENT Surgery.*

A multi-center, randomized, and controlled clinical study compared the efficacy and safety of two different types of post-operative packings in sinus surgery. The test products were ENTaxis (Algosteril) and Merocel. Clinical endpoints were epistaxis (degree of bleeding), pain on removal, and quality-of-healing.

Fifty (50) patients (100 nasal cavities) were enrolled in five ENT surgery departments. Every patient served as their own control by being treated with both test products. Clinical assessments were made during surgery (Day 1), on Day 2 (epistaxis and pain on removal), and on Day 9 (quality-of-healing).

Upon removal of the sinus packings on Day 2, ENTaxis was associated with both significantly less bleeding than Merocel ($p = 0.016$) and significantly less pain on removal ($p = 0.0001$).

Inspection of nasal mucosas eight days post-operatively revealed a trend towards more complete healing with ENTaxis (10 patients) compared to Merocel (5 patients).

Overall, compared to Merocel, ENTaxis was associated with statistically significant reductions in bleeding and pain on removal, as well as a trend towards improved overall healing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 1999

Les Laboratories Brothier, S.A.
C/O E.G. Dick & Associates
Evan Dick, Ph.D.
President
7527 Westmorland Ave.
St. Louis, MO 63105

Re: K984069
ENTaxis™ Nasal Packing
Dated: November 16, 1998
Received: November 16, 1998
Regulatory class: I
21 CFR 874.4100/Procode: 77 EMX

Dear Mr. Dick:

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 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). 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: ENTaxis™ Nasal Packing

Indications For Use:

ENTaxis™ Nasal Packing is intended for

- Epistaxis
- Post operative nasal packing

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984069

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)