DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2005

Mr. Bruno Ferreyrol
Regulatory Affairs Office
Novatech S.A.
Avenu du Vent des Dames
Z1 des Paluds
13685 Aubagne
France

Re: K971509
Trade/Device Name: ENDOXANE®
Regulation Number: 878.3720
Regulation Name: Prosthesis, tracheal, non-expandable, silicone
Regulatory Class: 2
Product Code: NWA
Dated: April 23, 1997
Received: April 25, 1997

Dear Mr. Ferreyrol:

This letter corrects our substantially equivalent letter of August 21, 1997.

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 (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 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 continue 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/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure: Indication for use statement for K971509.

510(k) Number (if known): K971509

Device Name: ENDOXANE

Indications For Use:

THE MAIN INDICATIONS ARE LISTED ACCORDING TO THEIR FREQUENCY:
-TRACHEOBRONCIAL TUMORS
-TRACHEAL STENOSIS WITH SCARRING
-BRONCIAL STENOSIS AFTER SURGICAL ANASTOMOTIC, ANASTOMOSES RESECTIONS OR PULMONARY TRANSPLANTATION
THESE STENOSES HAVE AS A COMMON CHARACTERISTIC THE IMPORTANCE OF THE EXTRINSIC COMPRESSION OR THE COLLAPSE OF THE CARTILAGINOUS WALL. THE INDICATION ALWAYS FOCUSES ON AN ENDOSCOPIC THERAPEUTIC ACTION WHETHER IT CONCERNS A RESECTION (LASER, CRYO, THERMO COGULATION) OR DILATATION. THE STENT INSERTION IS INDICATED ID THE ENDOSCOPIC RESECTION IS INCOMPLETE IN CASE OF A PERSISTENT EXTRINSIC COMPRESSION OR IF THE LUMEN OF THE AIRWAY IS INSUFFICIENT. THE MOST FREQUENT LOCATIONS ARE TRACHEAL.. THE LEFT MAIN BRONCHUS IS THE SECOND LOCATION FOLLOWED BY THE RIGHT MAIN BRONCHUS.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971509

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

NOVATECH

NEW BIOTECHNOLOGY FOR LIFE

K971509

510(k) Summary

Date of Application :	April 23rd, 1997
Applicant/Manufacturer Address :	NOVATECH S.A. Avenue du Vent des Dames ZI des Paluds 13685 Aubagne France
Telephone Number :	(33) 442 82 92 92
Fax Number :	(33) 442 82 92 27
Name of Contact Person:	Bruno FERREYROL Executive Director

The proprietary name or trade name of our medical device is ENDOXANE. The more common name of this device is an endo tracheal and endo bronchial stent, or Dumon Stent.

The Food and Drug Administration considers this device as a Class III - Tracheal Prosthesis.

The legally marketed device that we have cited for comparison is the ENDOXANE ® Stent, the same as ours, which was sold by our sole United States distributor, the Bryan Corporation (510K # K 4894380).

The device description can be found in Section IV Description of Device. In short, the ENDOXANE® is an endoscopy stent made of silicone. This stent, the most fitted in the world, is presented as a silicone tube with stubs allowing to avoid any movement. The non armed polysiloxane is covered with a new coating especially designed in order to keep its' flexibility which facilitates tolerance and evacuation of secretions.

A well-adapted ENDOXANE® does not move and cough reflexes are inhibited by reflex center saturation. The stubs prevent a direct contact between the stent surface and the mucus membrane and distribute the pressures among the small surfaces.

The main characteristics of ENDOXANE ® Stents can be divided into three main categories :

1. Histo compatibility : The medical grade silicone used for the manufacturing of ENDOXANE® is perfectly compatible during prolonged contact with trachea bronchial tissues.
2. Anti-encrustation and Anti-adhesion : NOVATECH has designed a new coating which guarantees high quality treatment of the surface favoring an easy flow of mucus. The surface is homogeneous and has a very fine grain. The parameter roughness is very weak. Furthermore, the surface treatment used avoids any tissue coloring and facilitates the positioning as well as the removal process. The extremities of the stents are manufactured according to a patented system which considerably reduces the risks of "mechanic" accumulation of mucus. The slope of the sides allows being non traumatic as no obstacle of mucus flow can be detected.
3. Anti-Migration System : All types of ENDOXANE® stents benefit from an exclusive and patented maintaining system. A perfect adhesion is assured by stubs found on the outer surface giving support to the surface and interpolating between the cartilaginous rings. This configuration prevents possible risks of stent migration if the size is well chosen.

The main indications according to their frequency are :

1. tracheobronchial tumors
2. Tracheal stenosis with scarring
3. Bronchial stenosis after surgical anastomotic, anastomoses resections or pulmonary transplantation.

These stenoses have, as a common characteristic, the importance of the extrinsic compression or the collapse of the cartilingeous wall. The indication always focuses on an endoscopic therapeutic action, whether is concerns a resection or dilation. The stent insertion indication is indicated if the endoscopic resection is incomplete, in case of a persistent extrinsic compression, or if the lumen of the airway is insufficient. The most frequent locations are tracheal. The left main bronchus is the second location, followed by the right main bronchus.

Our medical device has the same technological characteristics as the predicate device being that the two devices are the same. The only technological advancement that differs between the two devices is the new coating that we created in 1996. We have also developed three new shapes of the ENDOXANE Stents, each one with its particular use. The ENDOXANE BB Pediatric Stent was created in 1994 and is equipped with two lines of stubs opposite each other to facilitate the passage through the vocals cords. The ENDOXANE Y Stent is basically the same stent as Bryan Corporation but we added new dimension which are 15-12-12. This model is still used for carina pathologies associated with trachea and bronchus compression. The third new shape is the ENDOXANE ST Stenotic Stent (hourglass shape) which is perfectly adapted to post intubation benign stenosis.

The conclusion that one can reach concerning our stents is best stated in the study published in "The Journal of Bronchology" (3:6-10, 1996) about the placing of 1500 stents (Cavalière, Diaz, Dumon, Vergnon). Not a single case of compression was observed, even in cases of the most serious tumors (osteosarcoma, for example). In all of the cases of extreme compression, the stent that was oval shaped at the outset regained its round shape in less than two days. "Complications were uncommon, usually easily manage, and rarely life threatening. The main complications were emigration (9.5%)n obstruction by secretions.