

K961711  
1042

June 11, 1997

II 510(k) Summary of Safety and Effectiveness  
in Accordance with SMDA'90

April 29, 1996

B. Braun Medical, Inc  
824 Twelfth Avenue  
Bethlehem, PA 18018  
(610) 691-5400

CONTACT: Mark S. Alsberge, Regulatory Affairs Manager

PRODUCT NAME: Aspisafe Gastric Tube

TRADE NAME: Nasogastric Tube

CLASSIFICATION NAME:

General Hospital  
Class II, 80 BSS  
21 CFR 880.5440

SUBSTANTIAL EQUIVALENCE<sup>1</sup> TO:

510(k) number	Name	Applicant
K935688	Gastric Sump Tubes	Andersen Products

DEVICE DESCRIPTION:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Medical, Inc. intends to introduce into interstate commerce Aspisafe Gastric Tube. The Aspisafe Gastric Tube is designed to be used for the prophylaxis of pulmonary aspiration during induction and termination of general anesthesia.

<sup>1</sup> The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

MATERIAL:

The Aspisafe Gastric Tube is composed of materials that have been tested in accordance with Tripartite Guidance for Plastics and determined to be suitable for the intended use of this product.

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**SUBSTANTIAL EQUIVALENCE:**

The Aspisafe Gastric Tube is identical in materials, form, and intended use to the Gastric Sump Tubes currently marketed by Andersen Products. There are no new issues of safety or effectiveness raised by Aspisafe Gastric Tube.

**SAFETY AND EFFECTIVENESS:**

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release include, but are not limited to; physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP"s.



JUN 11 1997

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mark S. Alsberge  
Regulatory Affairs Manager  
B. Braun Medical, Inc.  
824 Twelfth Avenue  
P.O. Box 4027  
Bethlehem, Pennsylvania 18018-0027

Re: K961711  
Aspisafe Gastric Tube  
Dated: March 12, 1997  
Received: March 13, 1997  
Regulatory class: II  
21 CFR §876.5980/Product code: 78 BSS

Dear Mr. Alsberge:

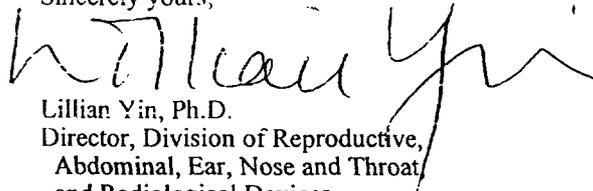
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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/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): K 961711

Device Name: Aspisafe Gastric Tube

Indications For Use:

The intended use is for the prophylaxis of pulmonary aspirations during induction and termination of general anesthesia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Salling  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K961711

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use