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1 of 5

Navion Biomedical Corp.  
Premarket Notification Information

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## I. GENERAL INFORMATION

Applicant: Navion Biomedical Corp.  
312 Tosca Drive  
Stoughton, MA 02072  
Establishment Registration # 1222311

Contact: Donald A. Kay  
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## II. DEVICE NAME

- 1) Trade Name: BioNavigation System for Placement of Enteral Feeding Tubes
- 2) Common Name: Enteral Tube Location System
- 3) Classification Name: unclassified

## III. DEVICE CLASSIFICATION

Unclassified

## IV. PURPOSE OF SUBMISSION

This submission describes a new device system for which a substantial equivalent determination is requested. The system includes a disposable MAPCath sensor stylet, which when inserted inside the lumen of an enteral feeding tube and used in conjunction with the Navion NAVIGATØR electronic instrument, allows the clinician to track the position and direction of the enteral feeding tube as it is moved inside of a patient during the tube placement procedure.

## V. PERFORMANCE STANDARDS

The FDA has promulgated no performance standards for this device.

## VI. APPLICATION BACKGROUND

Enteral feeding tubes are used in patients that can not consume an adequate diet orally and due to surgery, trauma or underlying disease can not be fed via the gastric system (stomach). To deliver nutritional support to these patients modified food is passed via an enteral feeding tube to the small bowel. Enteral tubes are initially placed in a similar manner to gastric feeding tubes by passing the tube through the patient's nasal passages into the esophagus and on into the stomach. Subsequently, enteral tubes are advanced out of the stomach, through the pyloric sphincter and into the duodenum and small bowel. In many instances, the tubes are allowed to naturally pass out of the stomach with normal digestive action. This can take 24 hours or longer. In some institutions special manipulations are performed to try to get the tube to move more rapidly. These can include the use of prokinetic drugs to stimulate the stomach to pass the tube more quickly.

Because feeding of the patient can not be initiated until the tube tip is in the duodenum or small bowel, frequent checks must be made on the tube tip location to determine the progress of the tube as it moves out of the stomach. Tip location is normally approximated by aspiration, auscultation or x-ray depending upon individual institution practice.

In aspiration, fluid is withdrawn from the tube and the pH and color of the fluid is determined. An acidic pH indicates the tube tip is still in the stomach / a pH greater than 6 and yellow color fluid indicates the tube tip is in the duodenum or small bowel.

In auscultation air is injected into the lumen of the tube and by listening for gurgling sounds emitted from the tube tip with a stethoscope an approximation of the tip location is made. Common anatomical markers are used to correlate the external position found with the stethoscope to the internal position of the tube tip. Generally, when the tube tip is found to have crossed the patient's midline (as the stomach is normally located on the patient's left side, the tip will be seen to pass from the left side to the right side) it is felt that the tube is exiting the stomach and entering the pyloric sphincter and duodenum. Both aspiration and auscultation are time consuming for the medical staff. The aspiration procedure may expose staff to potentially infectious fluids.

When x-ray is used to monitor the progress of the tube tip, the patient is usually subjected to multiple x-ray exposures. Typically, a portable x-ray unit must be repeatedly brought to the patient or the patient must be repeatedly brought to radiology. Because these procedures are expensive (x-rays) and time

consuming the number of times the tube position is checked may be limited. This can result in a delay of nutritional support for the patient.

## VII. PREDICATE DEVICE

Flexiflo Tube Placement Verifier (K922216), distributed by Ross Laboratories, Division of Abbott Laboratories, 625 Cleveland Ave., Columbus, OH 43215.

The Flexiflo Tube Placement Verifier is designed to aid in the placement of an enteral feeding tube by providing a clinician with real-time information as to the location of the tube tip during the placement procedure. Commonly used anatomical external markers used in auscultation procedures allow the clinician to approximate the internal position of the tube tip. Final tube position is confirmed using standard institutional procedures (x-ray, aspiration, or auscultation).

The system includes a sensor device permanently mounted inside the tip of a feeding tube and an electronic transmitter / receiver instrument that emits low level electromagnetic signals that are sensed by the sensor device in the tube tip. As the instrument is moved in the proximity of the sensor the instrument measures the change in response of the sensor and determines the relationship between the position of the sensor and the position of the instrument. The instrument provides a visual display indicating the direction the instrument should be moved to locate the tip of the tube and a second display to indicate when the instrument is directly over the tube tip.

In use, the tube is placed into the stomach following standard institutional procedures. To position the tube in the small bowel, the tube is either allowed to passively advance towards the pyloric sphincter due to normal digestive action or is manually advanced following individual institutional techniques. The tube tip position can be monitored using the instrument.

When the tube tip is seen to pass across the patient's midline it is exiting the stomach through the pyloric sphincter and entering the duodenum. As the tube advances and enters the duodenum, the tube tip will be seen to change direction and move towards the patient's feet. By continuing to allow the tube to advance, the tube tip will exit the duodenum and enter the small bowel. At this point the tube tip will move in a direction back toward the midline.

Once it is determined that the tube tip is in the small bowel, the tube tip position is confirmed using standard institutional procedures (e.g., x-ray, aspiration, or auscultation).

## VIII. PROPOSED DEVICE

BioNavigation System for Placement of Enteral Feeding Tubes, Navion Biomedical Corp., 312 Tosca Drive, Stoughton, MA 02072.

The BioNavigation System for Placement of Enteral Feeding Tubes is designed to aid in the placement of an enteral feeding tube by providing a clinician with real-time information as to the location and direction of the tube tip during the placement procedure. Commonly used anatomical external markers used in auscultation procedures allow the clinician to approximate the internal position of the tube tip. Final tube position is confirmed using standard institutional procedures (x-ray, aspiration, or auscultation).

The system includes a sensor device permanently mounted inside a sensor stylet (MAPCath) and an electronic transmitter / receiver instrument (NAVIGATØR) that emits low level electromagnetic signals that are sensed by the sensor device in the tip of the stylet. Prior to initiation of the enteral feeding tube insertion procedure, the MAPCath sensor stylet is positioned inside the lumen of the enteral tube adjacent to the standard stylet supplied with the tube. The sensor in the tip of the stylet is positioned near the tip of the tube and the stylet is locked in place.

As the instrument is moved in the proximity of the sensor the instrument measures the change in response of the sensor and determines the relationship between the position of the sensor and the position of the instrument. The instrument provides an audible and visual display indicating when the NAVIGATØR instrument is positioned directly over the tube tip and also provides an indication of the direction the tube tip is pointing.

In use, the tube is placed into the stomach following standard institutional procedures. To position the tube in the small bowel, the tube is either allowed to passively advance towards the pyloric sphincter due to normal digestive action or is manually advanced following individual institutional techniques. The tube tip position can be monitored using the instrument.

When the tube tip is seen to pass across the patient's midline it is exiting the stomach through the pyloric sphincter and entering the duodenum. As the tube advances and enters the duodenum, the tube tip will be seen to change direction and move towards the patient's feet. By continuing to allow the tube to advance, the tube tip will exit the duodenum and enter the small bowel. At this point the tube tip will move in a direction back toward the midline. Once it is determined that the tube tip is in the small bowel, the MAPCath sensor stylet

can be withdrawn. By withdrawing the MAPCath in a series of steps (e.g., withdrawn 10 cm at a time), the position and direction of the tube path can be reconfirmed using the NAVIGATØR instrument. The position and direction of the tube can be mapped on the anatomical chart supplied on the instructions for use to record the tube position. When the MAPCath is fully withdrawn it is discarded.

Once the tube has been placed, the tube tip position is confirmed using standard institutional procedures (e.g., x-ray, aspiration, or auscultation).

The NAVIGATØR instrument is the same instrument that received concurrence under K940385. The MAPCath sensor stylet received concurrence under K901263 and is currently marketed to place central venous catheters.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mr. Donald A. Kay  
President  
Navion Biomedical Corp.  
312 Tosca Drive  
Stoughton, MA 02072Re: K983476  
BioNavigation System for Placement of  
Enteral Feeding Tubes  
Dated: January 27, 1999  
Received: January 28, 1999  
Regulatory Class: II  
21 CFR 876.5980/Procode: 78 KNT

Dear Mr. Kay:

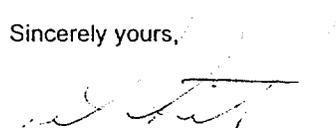
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

