



Food and Drug Administration  
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September 15, 2016

CORPAK MedSystems, Inc. A Division of Halyard Health  
Stephanie Wasielewski  
VP, RA/QA  
1001 Asbury Drive  
Buffalo Grove, IL 60089

Re: K162110  
Trade/Device Name: CORGRIP NG/NI Tube Retention System  
Regulation Number: 21 CFR§ 876.5980  
Regulation Name: Gastrointestinal Tube and Accessories  
Regulatory Class: II  
Product Code: KNT  
Dated: July 27, 2016  
Received: July 29, 2016

Dear Stephanie Wasielewski:

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 application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K162110

Device Name

CORGRIP NG/NI Tube Retention System

Indications for Use (Describe)

The CORGRIP Nasogastric/Nasointestinal (NG/NI) Tube Retention System is indicated for use with enteral feeding tubes of 8 FR and greater and NG decompression, suction and drainage tubes up to 18 FR to prevent inadvertent removal or displacement of the tubes for adult patients.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) Summary

### I. SUBMITTER

CORPAK MedSystems, Inc.  
1001 Asbury Dr.  
Buffalo Grove, IL 60089

P: 847 403-3400  
Contact: Stephanie Wasielewski  
Date prepared: July 27, 2016

### II. DEVICE

Trade name: CORGRIP NG/NI Tube Retention System  
Common name: Tube retention  
Classification name: Gastrointestinal tube and accessories (21 CFR 876.5980)  
Regulatory Class: II  
Product Code: KNT

### III. PREDICATE DEVICE

CORGRIP NG/NI Tube Retention System (K133599)

### IV. DEVICE DESCRIPTION

The CORGRIP NG/NI Tube Retention System is an accessory to prevent unwanted displacement or removal of nasogastric/nasojejunal tubes for adult patients by retaining the tube to the patient's nasal septum. The device consists of three main components: insertion (delivery) catheter, retrieval catheter, and tube clamp.

The catheters are placed in either nare of the patient and the clinician maneuvers the catheters to connect the magnets at the back of the patient's nasal septum. Both catheters have a flexible tip to aid in magnet connection. Once connection is made the magnet on the insertion catheter is pulled through the nare by the retrieval catheter. Both catheters are then removed from each nare until the ends of the umbilical tape are exiting either nare. The umbilical tape is then secured to the feeding tube with the provided clamp.

The proposed device adds the option of a 14, 16 and 18 Fr clamp.

### V. INDICATIONS FOR USE

The CORGRIP Nasogastric/Nasointestinal (NG/NI) Tube Retention System is indicated for use with enteral feeding tubes of 8 FR and greater and NG decompression, suction and drainage tubes up to 18 FR to prevent inadvertent removal or displacement of the tubes for adult patients.

#### VI. COMPARISON

The predicate device is identical to the proposed device with the exception of the additional clamp sizes (14,16 and 18Fr).

#### VII. Performance Data

The 14, 16, and 18 Fr CORGRIP NG/NI Tube Retention System clamp testing was conducted in a laboratory setting to establish verification of design requirements. Testing found that all clamps and materials met or exceeded design requirements established for the components when used with Covidien Salem Sump™ Dual Lumen Stomach Tubes. The following tests showed that the additional clamp sizes are substantially equivalent to those of the predicate device:

- Visual inspections
- Tether grip strength
- Tube grip strength
- Tube occlusion

Based upon the clamp test results, the proposed device design remains substantially equivalent to the predicate device.

#### VIII. Conclusions

There are no material or design changes being made to any components of the CORGRIP. In order to accommodate the larger suction tubes CORPAK has added three clamp sizes 14, 16 and 18 Fr.

The use, safety and effectiveness, of the proposed device clamps are substantially equivalent to the predicate device in terms of intended use, mode of operation, patient population, design, acceptance criteria, and biocompatibility.