



Food and Drug Administration  
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February 19, 2016

Talley Group Ltd.  
% Phil Bromley  
Consultant  
SGR Consulting Services  
8 Hollingworth Court, Turkey Mill, Ashford Road  
Maidstone, Kent ME14 5PP  
United Kingdom

Re: K151263  
Trade/Device Name: Venturi Gauze Wound Care Sets With Portal Drain  
Regulation Number: 21 CFR 878.4780  
Regulation Name: Powered suction pump  
Regulatory Class: Class II  
Product Code: OMP  
Dated: January 6, 2016  
Received: January 11, 2016

Dear Mr. Bromley:

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. 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 yours,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151263

Device Name

Venturi™ Gauze Wound Care Sets with Portal Drain

Indications for Use (Describe)

Venturi™ Gauze Wound Care Sets with Portal Drain are intended to be used with the Talley Group range of negative pressure wound therapy pumps. The Talley Group NPWT pumps are indicated use for patients with acute or chronic wounds that may be benefitted by the application of continual negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. The device is intended for use by qualified healthcare professionals in a healthcare environment.

NPWT is contraindicated for patients with:

1. Malignancy in the wound
2. Untreated osteomyelitis
3. Non-enteric and unexplored fistulas
4. Wounds with difficult haemostasis
5. Necrotic tissue with eschar present
6. Exposed vasculature, bone, nerves, or organs

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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# Venturi™ Gauze Wound Care Sets with Portal Drain

Ref: K151263

## 510(k) Summary

### 510(k) number K151263

This 510(k) summary is being submitted in accordance with the requirement of 21 CFR 807.92.

#### Summary

<b>Submitter's Identification:</b>	Talley Group, Ltd, Premier way, Abbey park industrial estate Romsey, Hampshire SO51 9DQ England
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<b>Owner/Operator Number:</b>	8010348
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<b>Email:</b>	rmacdonald@talleygroup.com
<b>Date of Summary:</b>	16 <sup>th</sup> February 2016
<b>Device/Proprietary Name:</b>	Venturi™ Gauze Wound Care Sets with Portal Drain
<b>Common Name:</b>	NPWT Dressing Kits
<b>Classification:</b>	Negative pressure wound therapy powered suction pump
<b>Product Code:</b>	OMP
<b>Product Class:</b>	II
<b>Code of Federal Regulation:</b>	21 CFR 878.4780
<b>Panel</b>	General & Plastic Surgery

<b>Substantial Equivalence:</b>			
<b>Manufacturer</b>	<b>Trade Name</b>	<b>Regulation &amp; Product Code</b>	<b>510(k) Number</b>
Talley Group	Venturi™ NPWT v.II Advanced Vacuum System	21 CFR 878.4780; OMP	K080897
Mölnlycke Health Care US, LLC	Avance® Foam Dressing Kits	21 CFR 878.4780; OMP	K122132



# Venturi™ Gauze Wound Care Sets with Portal Drain

Ref: K151263

## Description

### Description of Device

With the exception of the Portal Drain, there are no changes to the components in the currently marketed gauze dressing kits cleared in 510(K) K080897. The wound care sets connect to Negative Pressure Wound Therapy (NPWT) suction pumps to carry exudate from the wound.

The Venturi™ Gauze Wound Care Sets with Portal Drain consist of the following components:

**Venturi™ Gauze Wound Care Set:** Kerlix Antimicrobial gauze wound filler, adhesive film dressing, Portal Drain Assembly; 20ml saline solution and comes with measuring tape and instructions for use. These are supplied as sterile and single use.

The Venturi™ MINO Gauze Wound Care sets are have identical contents with the addition of a canister that attaches to the Venturi™ MINO NPWT device to contain the exudate.

The wound care sets include:

Product Code	Product Description
97-30-42-102	Venturi™ Gauze Wound Care Set with Portal Drain – Standard
97-30-42-109	Venturi™ Gauze Wound Care Set with Portal Drain – Large
97-30-42-114	Venturi™ MINO Gauze Wound Care Set with Portal Drain – Small

The Portal Drain assembly is consist of the portal drain which is adhered to a window dressing and is connected to the drain tube which connects at the other end to the NPWT pump via the canister connector assembly. There is a 90° drain tube guide and pinch clamp at the pump end of the assembly for additional safety.

The window dressing end of the Portal Drain Assembly is self-adhesive and a small hole is cut in the adhesive film dressing directly over the gauze and the Portal Drain Assembly is placed over the adhesive window dressing ensuring the portal drain is lined up with the hole. The other end of the tubing attaches to the pump to carry exudate from the wound.

### Indications for Use:

Venturi™ Gauze Would Care Sets with Portal Drain are intended to be used with the Talley Group range of negative pressure wound therapy pumps. The Talley Group NPWT pumps are indicated use for patients with acute or chronic wounds that may be benefitted by the application of continual negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. The device is intended for use by qualified healthcare professionals in a healthcare environment.

NPWT is contraindicated for patients with:

1. Malignancy in the wound
2. Untreated osteomyelitis
3. Non-enteric and unexplored fistulas
4. Wounds with difficult haemostasis
5. Necrotic tissue with eschar present
6. Exposed vasculature, bone, nerves, or organs.

### **Summary of the Determination of Substantial Equivalence & Performance Data**

All of kits components with the exception of the Portal Drain Assembly have been cleared for use as a NPWT dressing kit under K080897. The components used in the Venturi™ Gauze Wound



## Venturi™ Gauze Wound Care Sets with Portal Drain

Ref: K151263

Care Sets are identical to those in material, function and sterility (except the Portal Drain Assembly). The dressing kits in K080897 used a flat or channel drain that was placed underneath the adhesive film dressing and contacted the skin whereas the portal drain is placed over the adhesive film dressing and a small hole is cut above the gauze to ensure the portal drain and hole line up and there is no intended patient contact. The Portal Drain Assembly performs the same function as the flat or channel drain in the predicate (K080897).

The Venturi™ Gauze Wound Care Sets are equivalent in function to the Mölnlycke Avance® Dressing Kits incl. Transparent Film, Transfer Pad (K122132) and the Portal Drain Assembly is the equivalent of the Transfer Pad in the Avance® Dressing Kits (K122132). The Portal Drain Assembly and Transfer Pad are placed over a small cut hole on the adhesive film over the gauze and connect to the NPWT device to transport exudate to the canister in the pump.

The Venturi™ Gauze Wound Care Sets have equivalent intended uses to the predicates and are intended to contact the patient in the same way and for the same period of time and except for the Portal Drain Assembly have the same component parts as the predicate (K080897).

The component parts of the device and the predicates are all provided individually packaged, sterilised and have an equivalent shelf life. The devices have similar labelling and instructions for use.

The bench testing has demonstrated that the device does not introduce any additional risks when undertaking Negative Pressure Wound Therapy and meeting the intended use.

### **Clinical Testing**

No clinical data was required.

### **Conclusion**

Based on the information presented in this submission, it is concluded that the Venturi™ Gauze Wound Care Sets with Portal Drain are equivalent to the Avance® Dressing Kits (K122132) and the Venturi™ NPWT v.II Advanced Vacuum System (K080897) with respect to intended use, design and technological characteristics.

The Venturi™ Gauze Wound Care Sets with Portal Drain is as safe and effective as the predicate devices for facilitating Negative Pressure Wound Therapy and there are no new indications for use and therefore by following the FDA 510(k) "Substantial Equivalence" decision making process, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134783.htm> it is substantially equivalent to the predicate device.