



Food and Drug Administration  
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August 11, 2016

NICO Corporation  
Mr. Sean Spence  
Regulatory Affairs Manager  
250 East 96th Street, Suite 125  
Indianapolis, Indiana 46240

Re: K162075

Trade/Device Name: NICO TRIOwand  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: July 26, 2016  
Received: July 27, 2016

Dear Mr. Spence:

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,

**Christopher J. Ronk -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)

K162075

Device Name

NICO TRIOWand

Indications for Use (Describe)

The NICO TRIOWand is a disposable device designed to be used in soft tissue surgical procedures that require slow to rapid fluid evacuation and low energy output for the coagulation of tissue.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**10.0 510(k) SUMMARY**

**NICO TRIOwand™**

21 CFR §807.92

Date Prepared: 26 July 2016

**510(k) Number:**           K162075          

<b>Submitter/Manufacturer</b>	NICO Corporation 250 E. 96th Street, Suite 125 Indianapolis, IN 46240
<b>Primary Contact:</b>	Sean Spence, RAC Regulatory Affairs Manager Office: 317.660.7118
<b>Trade Name</b>	NICO TRIOwand
<b>Common/Usual Name</b>	Electrosurgical, cutting & coagulation & accessories
<b>Classification</b>	21 CFR §878.4400 (Class II)
<b>Product Code</b>	GEI
<b>Predicate Device</b>	K150993 – NICO TRIOwand

**Device Description**

The NICO TRIOwand is a surgeon controlled device that enables the delivery of bipolar coagulation via third-party electrosurgical generators. Coagulation occurs between two stationary insulated electrodes which are continuously drip irrigated during use. Second, the TRIOwand provides user controlled delivery of aspiration/vacuum for the evacuation of fluids from the surgical site. Third, the TRIOwand provides the user the ability to deliver irrigation for flushing the surgical field.

This submission covers a single configuration of the device:

- NICO TRIOwand - 4mm diameter, 14cm length, pre-bent (~30°)

The direct patient contacting materials consist of PEBA and stainless steel. The indirect contacting materials are PVC, TPV, polycarbonate, ABS, PC/ABS, silicone, and glue.

**Intended Use**

The NICO TRIOwand is a disposable device designed to be used in soft tissue surgical procedures that require slow to rapid fluid evacuation and low energy output for the coagulation of tissue.

**Comparison to Predicate**

The NICO TRIOwand is substantially equivalent to the NICO TRIOwand cleared under K150993. The subject iteration of the device and the predicate device are both used for soft tissue surgical procedures that require slow to rapid fluid evacuation and low energy output for the coagulation of tissue. The design changes include the addition of a stiffening sleeve, a smaller diameter drip line, a protective cap, and the ability to lock the slider in place.

**Technological Characteristics**

The following table compares the subject device and predicate device.

**Table 1: Technological Characteristic Comparison**

	<b>NICO TRIOwand (Bipolar Aspirating Wand (BAW))</b>	<b>NICO TRIOwand SUBJECT OF THIS SUBMISSION</b>
<b>510(k) #</b>	<b>K150993</b>	To be determined
<b>Intended Use/ Indications</b>	Disposable device designed to be used in soft tissue surgical procedures that require slow to rapid fluid evacuation and low energy output for the coagulation of tissue	Same
<b>Principles of Use</b>	Catheter-type device which includes four connections: 1) bipolar coagulation 2) aspiration 3) irrigation drip for electrodes 4) irrigation pathway for flushing the surgical field. Aspiration lumen used for removal of tissues/fluids from the surgical site. Irrigation drip lumens constantly bath the electrodes. Additional lumen exists to flush the surgical field.	Same
<b>Fundamental Technology</b>	Delivery of bipolar cauterization	Same
<b>Device design</b>	Coagulation occurs at/between two individual wire electrodes which are located at the tip of the device adjacent to the aspiration lumen.  Cavity (or annulus) around each electrode throughout the length of the device enables the continuous flow of saline (drip from bag).  Irrigation lumen exists for the manual delivery of fluids such as saline to the surgical field.  Sliding valve control over aspiration port on handle.	Same
<b>Cannula Stiffening Sleeve</b>	None	Stainless steel (gray) stiffening sleeve added to proximal portion of multi-lumen extrusion to provide additional rigidity.

<b>Electrode Drip Line Specifics</b>	Larger PVC ID tubing with polycarbonate Luer.	Smaller PVC ID tubing with polycarbonate Luer to help facilitate proper electrode drip rate.
<b>Protective Cap</b>	None	Santoprene cap added to distal tip to protect electrodes.
<b>Slider Mechanism for Aspiration Control</b>	Free moving slider	Free moving slider, with small tab added to lock slider in open position, if desired.
<b>Materials</b>	Stainless Steel, Pebax, Polycarbonate	Same + Bayer Makrolon Luer mentioned above for smaller electrode drip line + Santoprene for protective cap
<b>Biocompatible</b>	Externally Communicating Device in Direct Contact with Tissue/Bone/Dentin, Limited Duration.	Same
<b>Cross Sectional Analysis</b>	Total of 4 lumens: 2 for electrodes plus irrigation drip, 1 for aspiration, 1 for surgical field irrigation.	Same
<b>Diameter (shaft)</b>	4 mm	Same
<b>Lengths</b>	14 cm (angled shaft)	Same
<b>Configuration / System Components</b>	Terminally sterilized, fully disposable catheter-type device	Same
<b>Shipping configuration</b>	5 per box	2 per box
<b>Reusable or Single Patient Use</b>	Single Patient Use	Same
<b>Sterilization</b>	Gamma	Same
<b>Handheld/manual operation and placement</b>	Yes	Same
<b>Device Placement</b>	Via scope or unaided	Same
<b>Handle</b>	~14 cm length handle	Same
<b>Aspiration</b>	Fingertip controlled w/ the aid of a “slider” component which moves over a slot in the handle.	Same

The TRIOwand has the same fundamental technology as the predicate device. The technological and design differences do not raise new questions of safety or effectiveness and where applicable the nonclinical testing provides adequate means to assess the effects of the subject device as compared to the predicate.

**Nonclinical Testing**

The following tests were repeated to demonstrate that the proposed modifications met applicable design and performance requirements, and supports a determination of substantial equivalence:

- Biocompatibility per ISO 10993-1
  - Cytotoxicity, Sensitization, and Irritation
- Tensile Testing
- Predicate Device Testing Addendum (Irrigation/Flush Drip Measurement)
- Longevity Testing
- Usability/Human Factors Analysis
- Sterility Bioburden Addendum

- Shelf Life and Packaging Validation
- Specification Review & Dimensional Analysis
- Product Stability

### **Conclusion**

The subject device and the predicate are equivalent in terms of intended use and technological considerations. Risk assessments and testing activities have demonstrated that the design differences do not raise new questions of safety or effectiveness. Therefore, the conclusion drawn from these activities is that the NICO TRIOwand is as safe, as effective, and performs as well as or better than the legally marketed predicate TRIOwand.