



Food and Drug Administration
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April 23, 2015

NICO Corporation
Mr. Jay Dittman
Quality and Regulatory Director
250 East 96th Street, Suite 125
Indianapolis, Indiana 46240

Re: K150993

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: April 8, 2015

Received: April 15, 2015

Dear Mr. Dittman:

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" (21CFR 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,

Jennifer R. Stevenson -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)

K150993

Device Name

NICO TRIOwand

Indications for Use (Describe)

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.

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5.0 510(K) SUMMARY

NICO TRIOwand

21 CFR §807.92

Date Prepared: 06 March 2015

510(k) Number: K150993

Submitter/Manufacturer	NICO Corporation 250 E. 96th Street, Suite 125 Indianapolis, IN 46240
Primary Contact:	Jay Dittman Quality and Regulatory Director Office: 317.660.7118
Trade Name	NICO TRIOwand
Common/Usual Name	Electrosurgical, cutting & coagulation & accessories
Classification	21 CFR §878.4400 (Class II)
Product Code	GEI
Predicate Devices	Kirwan Bipolar Suction Coagulator; K960455 SilverGlide Non-Stick Bipolar Forceps; K992931

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 PEBAX[®] and stainless steel. The indirect contacting materials are Tygon[®], polycarbonate, ABS, PC/ABS, silicone, and Dymax glue.

Intended Use

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 Predicates

The NICO TRIOwand is substantially equivalent to the combination of Kirwan's Bipolar Suction Coagulator (K960455) and Stryker's SilverGlide Non-Stick Bipolar Forceps (K992931). The subject device and the Kirwan 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 Stryker SilverGlide predicate is also intended for electrocautery, as well as grasping and manipulation of tissue. The TRIOwand is not designed for grasping or manipulation of tissue, and this additional feature of the Stryker predicate is not critical to the primary electrocautery function of subject device.

Technological Characteristics

The following table compares the subject device and predicate devices.

Table 1: Technological Characteristic Comparison

Feature	NICO TRIOwand	Kirwan Bipolar Suction Coagulator	Stryker SilverGlide Non-Stick Bipolar Forceps
510(k) #	TBD	K960455	K992931
Intended Use/ Indications	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.	The <i>Bipolar Suction Coagulator</i> 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 the tissue i.e. neurosurgery, endoscopic, sinusoidal	Intended to facilitate grasping and manipulation of soft tissue and blood vessels and provide electrocautery in surgical procedures.
Principles of Use	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 irrigate the surgical field.	Catheter-type device which includes two connections: 1) bipolar coagulation 2) aspiration. Aspiration occurs through center lumen of device for the removal of tissues/fluids from the surgical site. Coagulation occurs at/between two tubular coaxial electrodes which are located at the tip of the device adjacent to the aspiration lumen.	Forceps-type device which includes two connections: 1) Bipolar coagulation 2) Irrigation drip for electrodes. Irrigation drip lumens constantly bathe electrodes.
Fundamental Technology	Delivery of bipolar cauterization	Identical	Identical

Table 1: Technological Characteristic Comparison (continued)

Feature	NICO TRIOwand	Kirwan Bipolar Suction Coagulator	Stryker SilverGlide Non-Stick Bipolar Forceps
Design	<p>Coagulation occurs at/between two individual wire electrodes which are located at the tip of the device adjacent to the aspiration lumen.</p> <p>Cavity (or annulus) around each electrode throughout the length of the device enables the continuous flow of saline (drip from bag).</p> <p>Irrigation lumen exists for the manual delivery of fluids such as saline to the surgical field.</p> <p>Sliding valve control over aspiration port on handle</p>	<p>Coagulation occurs at/between two tubular coaxial electrodes which are located at the tip of the device adjacent to the aspiration lumen.</p> <p>No means for continuous flow of saline at/around electrodes</p> <p>No lumen or means of delivery of fluids</p> <p>No sliding valve, aspiration controlled via extent of fingertip coverage over aspiration port</p>	<p>Coagulation occurs at/between the tips of the forceps as they are squeezed within proximity of one another.</p> <p>Lumens within handle of forceps enable the continuous flow of saline (drip from bag).</p> <p>No means of delivering irrigation to clear the surgical field</p> <p>No aspiration capabilities</p>
Materials	Stainless Steel, Pebax, Polycarbonate	Unknown	Stainless Steel
Biocomp.	Externally Communicating Device in Direct Contact with Tissue/Bone/Dentin, Limited Duration - Demonstrated	Identical	Identical
Cross Sectional Analysis	Total of 4 lumens: 2 for electrodes/irrigation drip, 1 for aspiration, 1 for surgical site irrigation	Total of 1 lumen for aspiration	Forceps configuration with a small lumen contained within one of the forceps for delivery of saline drip.
Shaft (dia.)	4 mm	5.5 mm	NA – no diameter (Forceps)
Lengths	1) 14 cm (angled shaft)	1) 14.2 cm (angled tip)	1) 19cm 2) 22cm 3) 25cm
Config./ Components	Terminally sterilized, single-use catheter-like device	Identical	Reprocessed, reusable forceps-type device
Shipping	5 per box	Identical	1 per box
Usage	Single Patient Use	Identical	Reusable device
Sterilization	Gamma	Identical	Onsite steam sterilization
Handheld/ manual operation and placement	Yes	Identical	Identical
Placement	Via scope or unaided	Identical	Identical
Handle	~14cm	~7cm	No defined handle, forceps-style device
Aspiration	Fingertip controlled w/ the aid of a “slider” component which moves over a slot	Fingertip controlled via slot which is occluded to produce aspiration	NA – no aspiration



The TRIOwand has the same fundamental technology as the predicate devices – they all deliver bipolar energy for the purpose of coagulation of tissue. Like the Kirwan predicate, the TRIOwand enables the delivery of aspiration for evacuation of fluids. Like the secondary predicate, the TRIOwand enables the delivery of irrigation drip to the electrodes. The technological 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 combined characteristics of the subject device as compared to the predicates.

Nonclinical Testing

The following tests were performed and demonstrate that the subject device met applicable design and performance requirements, and supports a determination of substantial equivalence:

- Biocompatibility per ISO 10993-1
 - Cytotoxicity, Sensitization, and Irritation
- Tensile Testing
- General Electrical Safety Testing per IEC 60601-1
- EMC Testing per IEC 60601-1-2
- High Frequency Surgical Equipment Testing per IEC 60601-2-2
- Ex-Vivo Animal Study for Comparison to Predicates
- Predicate Device Testing for Comparison to Predicates
- Longevity Testing
- Usability/Human Factors Analysis
- Design Validation/Simulated Use
- Sterility Validation
- Shelf Life and Packaging Validation

Conclusion

The subject device and the two predicate devices are equivalent in terms of intended use and technological considerations. Risk assessments, biocompatibility, electrical safety, bench testing, design validation, and compliance with recognized standards have demonstrated that any differences do not raise new questions of safety or effectiveness. Therefore, the conclusion drawn from the nonclinical activities demonstrate that the NICO TRIOwand is as safe, as effective, and performs as well as or better than the legally marketed predicate Kirwan and Stryker devices.