DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 28, 2014

nContact Surgical, Inc.
% Jane Ricupero
VP of Regulatory and Quality
1001 Aviation Parkway, Suite 400
Morrisville, North Carolina 27560

Re: K142084
Trade/Device Name: Epi-Sense Guided Coagulation Device With VisiTrax
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: September 4, 2014
Received: September 8, 2014

Dear Jane Ricupero,

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,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K**

Device Name: EPi-Sense® Guided Coagulation System with VisiTrax®

The EPi-Sense Guided Coagulation System with VisiTrax is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy using thoracoscopic, endoscopic, and laparoscopic surgical techniques.

The EPi-Sense Guided Coagulation System with VisiTrax may be used for temporary cardiac signal sensing and recording during surgery when connected to an external recording device.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary:

Application Date:	July 30, 2014
Sponsor:	nContact Surgical, Inc. 1001 Aviation Parkway, Suite 400, Morrisville, NC 27560
Establishment Registration Number:	3006142617
Correspondent:	Jane Ricupero VP of Regulatory & Quality 1001 Aviation Parkway, Suite 400, Morrisville, NC 27560
Contact Numbers:	Phone: 919 655-1355 Fax: 919 655-1690 E-mail: jricupero@ncontactinc.com
Device Proprietary Name(s):	EPi-Sense® Guided Coagulation System with VisiTrax® Model numbers: CDK-1411; CDK-1412; CDK-1413
Device Common Name:	Electrosurgical device and accessories
Device Classification:	21 CFR 878.4400 Class II
Product Code:	OCL
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Predicate Device	EPi-Sense Guided Coagulation System with VisiTrax, Model numbers: CDK-1411; CDK-1412; CDK-1413
Legally Marketed unmodified device 510k number	K120857 cleared Nov. 13, 2012

Device Description:

The EPi-Sense Guided Coagulation System with VisiTrax consists of a sterile, single-use, disposable coagulation electrode device (1cm, 2cm, & 3cm sizes provided) intended to be used to coagulate cardiac tissue. The flexible, cooled electrode device, with a suction stabilizer feature, transmits radiofrequency (RF) energy from an Electrosurgical Generator (non-sterile, re-useable) connected through an Instrument Cable (sterile). A temporary sensing electrode feature may be used with an off-the-shelf electrogram recording system with the use of an additional instrument cable (non-sterile). An accessory Cannula may be used to facilitate coagulation device access and visibility of the heart. **The Cannula accessory changes are the subject of this submission.**

Indications for Use:

Indications for Use: The EPi-Sense® Guided Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy using thoracoscopic, endoscopic, and laparoscopic surgical techniques.

The EPi-Sense® Guided Coagulation System with VisiTrax® may be used for temporary cardiac signal sensing and recording during surgery when connected to a temporary external recording device.

Description of Change for this Submission:

The following changes are being made to the Cannula Accessory for the EPi-Sense Guided Coagulation System with VisiTrax.

- Manufacturing process change for the cannula tip from an extrusion process to a molded process
- Material/part vendor changes
- Vacuum tubing wall thickness increase
- Addition of blue lumen marker
- Sterile barrier pouch sealing operation change of location
- Addition of two Cannula models

Comparison to Predicate Device and Summary of Technological Characteristics:

The nContact EPi-Sense System described in this submission is identical to the predicate nContact EPi-Sense System described in K120857 and has the identical intended use and technological characteristics.

- Coagulation Device functions, such as perfusion, suction, the RF electrode, and sensing electrodes are identical, with use of the same RF Generator and connecting cables.

- The Cannula accessory used with the EPi-Sense device has minor changes as described above with design features that are the same or slightly modified from the previous Cannula design.

Summary of Nonclinical Testing for Accessory Cannula:

Performance bench tests were executed to ensure that the Cannula accessory performed as intended and met design specifications in conjunction with the EPi-Sense Guided Coagulation System with VisiTrax.

The EPi-Sense device incorporates design features and specifications identical to those specified by the predicate device, there were no changes made to the coagulation device. The Cannula accessory with minor changes has completed testing to verify that no safety or effectiveness issues arise when using the coagulation device in conjunction with the Cannula.

The following tests were successfully completed to evaluate equivalence.

1. Biocompatibility testing per ISO 10993 for cannula accessory materials.
2. Sterilization validation per ISO 11137-2, Sterilization of Health Care Products – Radiation – Method VD Max for cannula accessory.
3. Reliability testing such as shipping and accelerated aging of packaged units.
4. Tensile testing of critical bonds and joints.
5. Flexion fatigue testing.
6. Electrical integrity testing for the cannula accessory used with the coagulation device to pertinent sections of IEC 60601-1-2.

Substantial Equivalence Conclusion:

nContact concludes that the modifications for the Cannula Accessory used with the EPi-Sense Guided Coagulation System with VisiTrax may be considered substantially equivalent or identical to the legally marketed predicate devices based on the results of design verification and validation. The indications for use, principle of operation, technology, performance specifications (as re-verified through design controls), and labeling and sterilization parameters have no substantial changes or modifications that significantly affect the safety or efficacy of the devices. **The Epi-Sense Guided Coagulation System with VisiTrax with Accessory Cannula is substantially equivalent to the stated predicate device.**