K082203

DEC 30 2008

Special 510(k) Summary:

Application Date:	August 1, 2008
Sponsor:	nContact Surgical, Inc. 1001 Aviation Parkway, Suite 400, Morrisville, NC 27560
Establishment Registration Number:	3006142617
Correspondent:	Jane Ricupero Director of Regulatory & Quality 1001 Aviation Parkway, Suite 400, Morrisville, NC 27560
Contact Numbers:	Phone: 919 655-1355 Fax: 919 655-1690 E-mail: jricupero@ncontactsurgical.com
Device Proprietary Name(s):	Numeris™ Tethered Coagulation System with VisiTrax® Model numbers: CSK-021; CSK-022; CSK-023; CSK-025
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	1. nContact Surgical Inc., nContact Coagulation System **(CSK)** Model numbers: CSK-100; CSK-200; CSK-500
Legally marketed unmodified device 510k number	**K063012 cleared Dec. 1/06** **K071819 cleared July 26/07** (will be used for packaging comparison only)

Device Description:

The modified nContact system, "Numeris Tethered Coagulation System with VisiTrax", consists of a sterile, single-use, disposable coagulation electrode device (1cm, 2cm, 3cm, & 5cm 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).
The functionality of this System is the same as the cleared predicate system, however two addition RF coil electrode lengths have been added to the product offering (1cm and 3cm).

Indications for Use:

The Numeris Tethered Coagulation System with VisiTrax is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during open-chest cardiac surgery.
The indications for use of this System are the same as the cleared predicate system.

Technological Characteristics:

The Numeris Tethered Coagulation System with VisiTrax has minor material changes and minor design modifications with the main technological characteristics of transmitting RF energy from an electrosurgical generator connected by an instrument cable to a coagulation electrode remaining identical to the predicate device.

Performance Data:

Performance bench tests were executed to ensure that the Numeris Tethered Coagulation System with VisiTrax performed as intended and met design specifications.

Substantial Equivalence Conclusion:

This special 510(k) proposes that the material and design modifications for the Numeris Tethered Coagulation System with VisiTrax may be considered substantially equivalent to the legally marketed unmodified nContact Coagulation System (previously cleared under K063012 on Dec. 1, 2006) 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), labeling and sterilization parameters are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

We believe that the Numeris Tethered Coagulation System with VisiTrax is substantially equivalent to the unmodified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 2008

nContact Surgical, Inc.
c/o Jane A. Ricupero
Director of Regulatory and Quality
1001 Aviation Parkway, Suite 400
Morrisville, NC 27560

Re: K082203
Trade/Device Name: Numeris Coagulation System with Visitrax (Gen 3 with Tether)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OCL
Dated: December 4, 2008
Received: December 5, 2008

Dear Ms. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. J. Villeberme

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): **K082203**

Device Name: Numeris™ Tethered Coagulation System with VisiTrax®

Indications for Use: The Numeris™ Tethered Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy during open-chest cardiac surgery.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. J. Hollenbeck

(Division Sign-Off)
Division of Cardiovascular Devices

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