510 (K) Submission Summary

FEB - 4 2011

NuVue ColorMark™ Needle (K101312)

Common/Classification Name: Ultrasonic Locator of Interventional Needles, 21CFR 892.1550

Contact: Roger S. Kolasinski, Prepared: February 3, 2011

I. Legally marketed Predicate Devices

The NuVue ColorMark™ Needle is substantially equivalent to the EchoTip Needle Guidewire Introducer Needle (K031173) for ultrasound imaging visibility and to the ColorMark™ Visualization System (K926351) for Color flow Doppler Ultrasound imaging visibility.

II. Intended Use

Indications for Use:

The NuVue ColorMark™ Needle is intended for use when one desires visualization of an interventional needle (e.g. biopsy needle) on B-scan ultrasound screens which have color flow Doppler imaging capability.

The NuVue ColorMark™Needle is indicated for use in clinical applications and at anatomical sites for which the biopsy needle and the ultrasound system have received marketing clearance by the FDA.

III. Substantial equivalence Summary

The technology used in the NuVue ColorMark™Needle is substantially equivalent to that used in the ColorMark™ Visualization System that was previously approved under K926351. The NuVue ColorMark™Needle has improved ergonomics with similar technology and performance as its predecessor in that it presents the image of the needle as a colored line on the B-scan screen, by making the needle vibrate at low (sonic) frequencies. The Needles purchased by NuVue therapeutics have the same characteristics as similar type, gauge, and length needles for similar applications. These new characteristics do not raise new types of safety or effectiveness questions.

IV. Device description

The NuVue ColorMark™Needle combines a hand-piece and echogenic needles like its predicates. The NuVue ColorMark™Needle is intended to allow the visualization by ultrasound of a needle- such as biopsy needle- inserted into the body. The principle is that the needle is made to vibrate at low sonic frequencies (<1 kHz), which makes it visible on a Doppler Color-flow system, since the vibration of the needle appears as motion to the Doppler system.

As Stipulated, NuVue's ColorMark™ Needle, a hand-held needle device, consists of the driving hand-piece and integrated needle. The system is a self-contained, battery-operated, and single-use device that integrates and vibrates interventional biopsy needle(s). The hand-piece accommodates a range of NuVue Therapeutics compatible biopsy needles that fit within its integrated sleeve. The sleeve is the guide and vibration transmitter for the needle.

The NuVue ColorMark™Needle is an electro-mechanical needle device. The mechanical coupling of the needle with the hand-piece exciter is mediated by two electromagnets that make the hand-piece sleeve to vibrate in an orbital-like motion, through a phasing of the coils +- 90 degrees apart. This motion is transferred to the interventional needle that is coaxially catheterizing the hand-piece sleeve. This allows for the representation of color Doppler imaging in 360 degrees of rotation of the needle while it is in NuVue's new hand held interventional driver device and in the on position. The needle motion stimulates the Doppler motion sensing function of the imager to display colors corresponding to turbulent fluid motion pattern in close vicinity with the biopsy needle.

NuVue Therapeutics will purchase in bulk needles designated by application (biopsy, aspiration, other), needle type (Chiba, Franseen, spinal, other), needle gauge (19 to 27). The needle device, as stipulated, is a single use, hand-piece that integrates and guides the needle for lengths of tissue insertion from 10 to 20 cm. The needle device will be repackaged as a single use device, sterilized with Ethylene Oxide, and distributed commercially under the NuVue Therapeutics, Inc. Name, with the stipulation on the packaging, do not reuse or re-sterilize.

V. Testing

NuVue Therapeutics has carried out energy and imaging performance testing on the NuVue ColorMark™ Needles.

The changes implemented into the NuVue ColorMark™ Needle do not introduce any added safety risk nor do they lessen any imaging performance compared to the predicate devices. NuVue has the ability of Quadriture, which allows visualization of any of its needles in a 360 degree visualized capability, compared to the cleared ColorMark™ Visualization System, who's vibratory signal was designed in a linear responsibility, demanding the operator of the device to always be assured of the orientation of the needle to the head of the Doppler Transducer, per the manufactures mandates.

A detailed analysis of the safety of NuVue's device shows no addition risk issues. In case of failure of the device, Color Doppler visualization may be lost, but the needle is still visible and can be followed by conventional techniques.

Our imaging studies show that NuVue's ColorMark™ Needle is effective in the visualization of image of the biopsy needle, and can be easily used by the operator.

VI. Conclusion

This premarket submission has demonstrated Substantial equivalence as defined by the Federal Food and Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NuVue Therapeutics, Inc.
% Mr. Roger S. Kolasinski, CEO
11135 Sedgefield Road
Fairfax, Virginia 22030

FEB - 4 2011

Re: K101312
Trade/Device Name: NuVue Colormark™ Needle
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN
Dated: December 15, 2010
Received: December 17, 2010

Dear Mr. Kolasinski:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K101312

Device Name: NUVUE COLORMARK™ NEEDLE

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101312