



Food and Drug Administration
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Neocoil, LLC
Michael Leigh
Director, Regulatory/Quality
N27 W23910a Paul Rd.
Pewaukee, Wisconsin 53072

June 16, 2016

Re: K160350
Trade/Device Name: ECG CT Gating Device
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 2, 2016
Received: February 8, 2016

Dear Michael Leigh:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned to the left of the typed name.

For

Robert A. Ochs
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name

ECG CT Gating Device

Indications for Use (Describe)

To be used in conjunction with a CT scanner to acquire gated cardiac images. The product is an aid to the acquisition of CT cardiac scans.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5. Traditional 510(k) Summary

5.1. Applicant

NeoCoil, LLC
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Pewaukee, WI 53072 USA

5.2. Contact

Michael Leigh
Director, Regulatory/Quality
262-522-6127 (direct)
261-347-1251 (fax)
Mike.leigh@neocoil.com

5.3. Preparation Date

01/28/2016

5.4. Name of Device

- Proprietary Name: ECG CT Gating Device
- Common Name: Computed tomography x-ray system (accessory)
- Classification: 21 CFR 892.1750, Product Code JAK

5.5. Model Numbers

NeoCoil Model Number	NeoCoil Model Name
NC065000	Physiologic Acquisition Module (PAM)
NC080000	Receive Interface Module (RIM)
NC065601	ECG lead wires

5.6. Device Description

The NeoCoil ECG CT Gating Device (ECGD) is a product used to acquire electrocardiogram (ECG) data from a patient and to generate and supply ECG waveform and triggering pulses to the CT scanner to aid in cardiac scanning. The ECGD product includes a Physiologic Acquisition Module (PAM) that connects to the patient using ECG lead wires (Figure 3.), acquires ECG data, processes the ECG data, and wirelessly transmits the data to the Receive Interface Module (RIM). The RIM will wirelessly receive data from the PAM, create analog ECG waveform and trigger pulse mark, and interfaces with the scanner. The ECG waveform and trigger marks can be seen on the scanner console.

The System is compatible with Toshiba Aquilion ONE and Aquilion PRIME CT scanners.

5.7. Predicate Device

- ECG-Gating System for Aquilion CT Scanner, TSX-101A, K991766 as cleared on 08/10/1999.

5.8. Comparison to Predicate

The NeoCoil ECG CT Gating Device is similar in physical, performance, design and material characteristics to the legally marketed device, ECG-Gating System for Aquilion CT Scanner, TSX-101A, K991766 as cleared on 08/10/1999.

The NeoCoil ECG CT Gating Device is an accessory to the Toshiba Aquilion CT Scanner that allows scans to be triggered by ECG-gating signals. The Toshiba ECG-Gating System is an upgrade to previously cleared Aquilion CT Scanner, TSX-101A. This upgrade will allow scans to be triggered by ECG-gating signals.

The Indications for Use are consistent with the capabilities of the predicate device, ECG-Gating System for Aquilion CT Scanner, TSX-101A, K991766 as cleared on 08/10/1999.

The following table provides a comparison of technology and performance.

Technology			
Configuration	ECG leads provide wired connection to monitor connected to scanner interface	ECG leads provide wireless connection to receiver connected to scanner interface	Equivalent.
Source of gating signal	Third party monitors (e.g. Ivy Biomedical model 7600 – K110987)	NeoCoil ECG CT Gating Device	Equivalent.
Number of lead wires	Four	Four	Identical
Method	Amplitude	Vector	Equivalent performance
Pacer pulse rejection	Width: 0.1 to 2 ms at ± 2 to ± 700 mV	Width: 0.1 to 2ms at ± 2 mv to ± 700 mv	Identical
Gating Indications	Lead Off Check Lead	Lead Off Wireless Connection Battery Status	NeoCoil use is limited to gating only; not monitoring. NeoCoil includes additional indicators for wireless and battery status.
Defibrillator Protection	IEC 60601-2-27: Edition 3.0 compliant	IEC 60601-2-27: Edition 3.0 compliant	Identical
Performance			
Heart rate range	10 to 300 BPM (Adult) $\pm 1\% \pm 1$ BPM	30 to 200 BPM ± 2 BPM	NeoCoil use is limited to gating only; not monitoring. Range is limited based on clinical relevance to gated scans.

Arrhythmias	1. Normal Sinus Rhythm 2. Sinus Arrhythmia (heart rate variability) 3. Atrial Fibrillation (AFib) 4. Paroxysmal Supraventricular Tachycardia (PSVT) 5. Bradycardia 6. Second-Degree Atrioventricular block	1. Normal Sinus Rhythm 2. Sinus Arrhythmia (heart rate variability) 3. Atrial Fibrillation (AFib) 4. Paroxysmal Supraventricular Tachycardia (PSVT) 5. Bradycardia 6. Second-Degree Atrioventricular block	Identical
Trigger Output	0V baseline, with +5V trigger, 100ms pulse width	0V baseline, with +5V trigger, 100ms pulse width	Identical, as required by Toshiba scanner
Performance Index ¹	No claims	Provides trigger pulses to the scanner, corresponding with R wave peaks, with an accuracy (performance index) of $\geq 98\%$.	Equivalent. The performance index is 98%. In the rare case of a mistrigger during image acquisition, the operator of the CT scanner can manually adjust the identification of the QRS complex and then initiate image reconstruction. The same manual editing procedure is used for both devices.

Clinical testing demonstrates that the differences in the devices do not affect the safety and/or the effectiveness of the device when used as labeled.

5.9. Indications for Use

To be used in conjunction with a CT scanner to acquire gated cardiac images. The product is an aid to the acquisition of CT cardiac scans.

5.10. Intended Use

The ECG CT Gating Device is intended to be used in conjunction with a CT scanner to acquire cardiac images.

5.11. Testing

The following data has been submitted, referenced or relied on to demonstrate that the NeoCoil ECG CT Gating Device is safe and effective. The devices' performance meets the requirements of pre-defined acceptance criteria and intended uses.

Performance testing - Bench:

Test	Pass/Fail Criteria	Result
ECG CT Gating Device Compatibility Testing	Gating Device is Compatible with Toshiba Aquilon CT scanners.	Pass
ECG CT Gating Waveforms and Triggers	Device accurately produces waveforms and triggers through specified range and arrhythmias.	Pass
ECG CT Gating Device Interference Testing	Potentially interfering devices in the CT environment do not interfere with the ECG CT Gating Device.	Pass

Test	Pass/Fail Criteria	Result
ECG CT Gating Device Quality of Service	The ECG Gating Device provides a safe and effective wireless quality of service in the CT environment.	Pass

Published Standards testing:

Standard	Purpose
IEC 60601-1	Electromechanical safety
IEC 60601-1-2	Electromagnetic compatibility
IEC60601-1-6	Usability
IEC 60601-2-44	Electromechanical safety
ISO 10993-1	Biocompatibility

Performance testing - Clinical:

The clinical data represent the indicated use of the device. The cross-sectional images generated demonstrate the expected cardiac anatomy.

No adverse events were reported during clinical performance testing; the ECG CT Gating Device demonstrated performance adequate to support the Indications for Use.

5.12. Conclusion

This submission demonstrates that the Indications for Use are in line with the predicate device to be used in conjunction with a CT scanner to acquire gated cardiac images. The product is an aid to the acquisition of CT cardiac scans. As such, the NeoCoil ECG CT Gating Device is equivalent to their predicate, ECG-Gating System for Aquilion CT Scanner, TSX-101A, K991766 as cleared on 08/10/1999.