K131431
Page 1 of 6

MOBIUS

510(k) Summary

This 510(k) Summary of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92.

1. **Submitter:**

Mobius Imaging, LLC
323 West Main Street
Ayer, MA 01432
USA

SEP 26 2013

Contact:
Norma LeMay
Director of Regulatory Affairs
Telephone: 978-391-9644
Fax: 978-772-3441
Email: nlemay@mobiusimaging.com

Date of Preparation: August 26, 2013

2. **Device Name & Regulatory Classification:**
Proprietary or Trade Name: AIRO™ CT System
Classification Name: Computed Tomography X-ray System
Product Code: 90 JAK
Device Classification: Class II
Regulation Number: 21 CFR 892.1750

3. **Predicate Device(s):**
The legally marketed device to which substantial equivalence is being claimed is as follows:
    - Neurologica NL4000 BodyTom™ CT System – Premarket Notification K102677 (cleared on March 24, 2011, product code 90 JAK)

4. **Device Description:**
The Mobius Airo is a mobile high resolution Computed Tomography (CT) System similar to the NL4000 BodyTom CT System. The Airo has a large-diameter bore designed for intra-operative use; the main features include a 107cm bore, with a 51.2cm field of view (FOV). The Airo has two modes of operation; transport and scanning. In its scanning mode, translation along the longitudinal axis is achieved through movement of the gantry along the length of the system base (rather than through movement of the patient support table).

The lightweight translating gantry consists of a rotating disk with a solid state x-ray generator, solid state detector array (that includes detector modules that consist of a layered Cadmium Tungstate (CdWO4) and Photodiode Array). Each detector module includes a 32 x 16 pixel scintillator array that produces scintillation events responsive to irradiation by X-rays. The Airo also includes a collimator, control computer, communications link, data acquisition system, reconstruction computer, power system, brushless DC servo drive system (disk rotation), and a DC brushless servo drive system (translation).

The power system consists of batteries which provide system power while unplugged from a standard power outlet (e.g., during transport of the System and also during scanning). The base has retractable rotating caster wheels and electrical drive system so the System can be easily moved to different locations.

In addition, the System has the necessary safety features such as emergency stop button, X-ray indicators, interlocks, patient alignment lasers, and 110 percent X-ray timer. The software helical reconstruction is based on an exact filtered-back projection algorithm.

5. **Indications for Use:**

The AIRO™ is intended to be used for non-contrast X-ray computed tomography applications for anatomy that can be imaged in the 107cm aperture excluding pediatric patients and patients weighing over 400 lbs (182 kg).

Airo is contraindicated as the principal means of guidance during surgical procedures. The physician must verify navigation accuracy using known anatomical landmarks or an equivalent verification method when used in surgical procedures.

6. **Comparison of Technological Characteristics with the Predicate Device:**

As detailed in Section 12 of this 510(k) Premarket Notification, the Airo CT System, for its intended use, is of comparable type in design, material, functionality, technology and is considered substantially equivalent to the NeuroLogica BodyTom™ CT System (K102677) based on the following comparison. Most importantly, the differences noted below raise no new issues of safety or effectiveness based on all testing performed and presented in this 510(k) submission.

Model Name	**Airo™ CT System**	**NL 4000 BodyTom™ (K102677)**
Technological Characteristics		
Indications for Use	The AIRO™ is intended to be used for non-contrast X-ray computed tomography applications for anatomy that can be imaged in the 107cm aperture excluding pediatric patients and patients weighing over 400 lbs (182 kg). Airo is contraindicated as the principal means of guidance during surgical procedures. The physician must verify navigation accuracy using known anatomical landmarks or an	The NL4000 BodyTom™ is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 85cm aperture

Model Name	Airo™ CT System	NL 4000 BodyTom™ (K102677)
Technological Characteristics		
	equivalent verification method when used in surgical procedures.	
Aperture (cm)	**107**	85
Image Field of View (cm)	**51.2**	60
Detector Material	Solid State CdWO4	Solid State CdWO4
Detector Configuration	32 x **2.0mm**	32 x 1.25mm
Spatial Resolution for Sharpest Clinical Algorithm **(lp/cm at 2%)**	**6.9**	12.0
X-ray Tube Type	Rotating Anode	Rotating Anode
Heat Storage (MHU)	**2.3**	3.5 and 5.0
X-ray Tube Cooling	**Liquid (50% Water, 50% Propylene Glycol)**	Oil
X-ray Fan Angle (deg)	**45**	54
Max X-ray Power (kW)	**32**	42
Rotating Speed (seconds)	**2**	1, 2
Gantry Weight (kg)	**1000 (approx)**	1200
Transfer of electric current	**Data Dock system**	Slip ring
Mechanism to translate Gantry	**Rails on Mobile Base System**	On floor treads
Mobile	Yes (motorized)	Yes (motorized)
Wheels (casters)	**Wheels (3 inch)**	Wheels (6 inch)
Input Voltage	1 phase **100**-240 volt	1 phase 110-240 volt
PACS/DICOM 3.0	Yes	Yes
2D Scout	Yes	Yes
Bolus tracking	**No**	Yes
Dynamic Scan	**No**	Yes
Axial/Helical	**Helical**	Both
MPR	Yes	Yes
3D Viewing	**No**	Yes
Patient Table	**Yes (Trumpf table column integrated with base)**	Optional, not required
Scan Motion	Scanner Moves	Scanner Moves

Model Name	Airo™ CT System	NL 4000 BodyTom™ (K102677)
Technological Characteristics		
Laser Alignment	Patient Alignment	Patient Alignment
X-ray warning light	Yes	Yes
110% X-ray Timer	Yes	Yes
Emergency Stop	Yes	Yes
Operator X-ray On Switch	Yes	Yes
Quality Test Phantom	Yes	Yes
Login ID/password	Yes	Yes
Administrator Privileges	Yes	Yes
Dose Display	Yes	Yes
Dose Report/Audit	Yes	Yes
Protocol Override Protection	Yes	Yes
Protocols by weight/body region	Yes	Yes (includes Age)
QA Test Report	Yes/Third Party Software	Yes
Operating System	Microsoft Windows	Microsoft Windows
Where Used	Mobile or Fixed Radiology, ICU, ED, Surgical, Clinic, Office	Mobile or Fixed Radiology, ICU, ED, Surgical, Interventional, Clinic, Office

7. General Safety and Effectiveness Concerns:

Identical to its predicate device, all components of the Airo CT System are subject to Federal Diagnostic Equipment Performance Standard and applicable regulations of 21 CFR Part 1020.30 and 1020.33 and will be certified to meet those requirements. An Initial Report will be filed with the Center for Devices and Radiological Health (CDRH) according to 21 CFR 1002.10 prior to commercialization of the Airo CT System, respectively.

To minimize electrical, mechanical and radiation hazards, Mobius adheres to recognized and established industry practices. Additionally, the Airo CT System was designed and tested to the following FDA recognized International harmonized standards:

- **IEC 60601-1** Issued: 2005/01/01 Ed:3 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2** Issued: 2007/03/01 Ed:3 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

- **IEC 60601-1-3** Issued: 2008/01/22 Ed:2 Medical Elec. Equipment - P. 1: General Req. for Safety 3. Collateral Standard: General Req. for Radiation Protection in Diagnostic X-Ray Equipment

- **IEC 62366** Issued: 2007/10 Ed:1, Medical devices – Application of usability engineering to medical devices

- **IEC 60601-2-44** Issued: 2009/02/25 Ed:3 Medical Electrical Equipment - Part 2-44: Particular Requirements for the basic safety and essential performance of X-ray Equipment for computed Tomography

- **IEC 61223:2004 –** Evaluation and routine testing in medical imaging departments - Part 3-5 Acceptance Tests – Imaging Performance of Computed Tomography X-ray equipment

- **IEC 60825-1:2007** – Safety of laser products

- **IEC 62133:2002:** Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

- **UL 1642:1995:** Standard for Lithium Batteries

Relating to concerns regarding unintentional radiation exposure, the Airo CT System, like the NL4000 BodyTom System, has software safeguards such as: ID password/login, dose display/reporting, safety warning to prevent excessive dose, protocol protection and required quality assurance testing.

8. **Determination of Substantial Equivalence:**

Summary of Non-clinical tests:
The Airo CT System complies with the voluntary harmonized standards as detailed above and in Section 9 and 17 of this 510(k) Premarket Notification. In addition, the following quality assurance measures were applied to the development of the System:

- Risk Analysis
- Design Reviews
- Design Verification Testing
- SW Unit Integration Testing
- System Software Verification & Validation Testing
- Image Performance & Radiation Safety Testing
- Electrical Safety, Mechanical & Stability Testing
- EMI/EMC Testing

Summary of Clinical Tests:

A Non-Significant Risk (NSR) study was performed to determine the diagnostic image quality of the Airo CT System for typical intended use anatomy. Once collected, all images were independently and subjectively reviewed and found to be of diagnostic image quality. All images, as well as the final report, are provided in Section 20 of this 510(k) submission.

The results of all testing performed indicate that the Airo CT System meets the acceptance criteria and is substantially equivalent to the currently cleared predicate device (Neurologica BodyTom CT System).

9. **Conclusion:**

Based upon the above considerations, including all testing presented in this 510(k) submission, Mobius considers the Airo CT System to be as safe, as effective, and performance is substantially equivalent to its predicate device. We also believe the Airo CT System raises no new issues of safety and/or efficacy and the device performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mobius Imaging, LLC
% Ms. Norma J. LeMay
Director of Regulatory Affairs
323 West Main Street
AYER MA 01432

September 26, 2013

Re: K131431
Trade/Device Name: AIRO™ Computed Tomography (CT) X-ray System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: August 26, 2013
Received: August 27, 2013

Dear Ms. LeMay:

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 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. 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,

Michael D. O'Hara for

Janine M. Morris
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): K131431

Device Name: AIRO™ Computed Tomography X-ray System

Indications for Use:

The AIRO™ is intended to be used for non-contrast X-ray computed tomography applications for anatomy that can be imaged in the 107cm aperture excluding pediatric patients and patients weighing over 400 lbs (182 kg).

Airo is contraindicated as the principal means of guidance during surgical procedures. The physician must verify navigation accuracy using known anatomical landmarks or an equivalent verification method when used in surgical procedures.

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 *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131431