



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

Mobius Imaging, LLC  
% Ms. Norma LeMay  
Regulatory Affairs Contractor  
2 Shaker Road  
SHIRLEY MA 01464

April 19, 2016

Re: K160126

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: March 7, 2016  
Received: March 8, 2016

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 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 above the typed name of the signatory.

For

Robert Ochs, Ph.D.  
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)  
K160126

Device Name  
AIRO® Computed Tomography (CT) X-ray System

### Indications for Use (Describe)

The AIRO® is intended to be used for 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).

### **Contraindications:**

Airo is contraindicated as the principal means of guidance during invasive procedures when real-time imaging is needed (e.g., CT Fluoroscopy procedures). In addition, the physician must verify navigation accuracy using an adequate verification method when used with Navigation Systems during surgical procedures.

### 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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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# 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  
2 Shaker Road, Suite F100  
Shirley, MA 01464  
USA

**Contact:**

Norma LeMay  
Regulatory Affairs Consultant  
Telephone: 978-391-9644  
Email: [nlemay@mobiusing.com](mailto:nlemay@mobiusing.com)

**Date of Preparation:** March 7, 2016

**2. Device Name & Regulatory Classification:**

Proprietary or Trade Name: AIRO® Computed Tomography (CT) X-ray 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:

- *Airo Mobile CT System – Premarket Notification K131431 (cleared on September 26, 2013, product code 90 JAK)*

**4. Device Description:**

The Mobius Airo is a Mobile Intraoperative Computed Tomography (CT) System. The Airo has a large-diameter bore designed for intraoperative 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 (both helical and axial in patient mode). 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 (CdWO<sub>4</sub>) 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 and axial reconstruction algorithms are both based on an exact filtered-back projection.

## **5. Indications for Use:**

The AIRO<sup>®</sup> is intended to be used for 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).

### **Contraindications:**

AIRO is contraindicated as the principal means of guidance during invasive procedures when real-time imaging is needed (e.g., CT Fluoroscopy procedures). In addition, the physician must verify navigation accuracy using an adequate verification method when used with Navigation Systems during surgical procedures.

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

As detailed in Section 12 of this 510(k) Premarket Notification, the modified Airo CT System, for its intended use, is of comparable type in design, material, functionality, technology and is considered substantially equivalent to its baseline device Airo CT System (K131431, cleared on September 26, 2013) based on the following comparison.

Most importantly, the differences noted below and/or in the comparison table raise no new issues of safety or effectiveness based on all testing performed and presented in this 510(k) submission:

- Sequential Axial Scanning Mode
- Tube Current Modulation Feature (Helical only)
- Metal Artifact Reduction Algorithm

<b>Model Name</b>	<b>Airo® CT System (subject of this 510(k))</b>	<b>Airo® CT System (K131431)</b>
<b>Technological Characteristics</b>		
Indications for Use	<p>The AIRO is intended to be used for 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).</p> <p>Airo is contraindicated as the principal means of guidance during invasive procedures when real-time imaging is needed (e.g., CT Fluoroscopy). In addition, the physician must verify navigation accuracy using an adequate verification method when used with Navigation Systems during surgical procedures.</p>	<p>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).</p> <p>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.</p>
Aperture (cm)	107	107
Image Field of View (cm)	51.2	51.2
Detector Material	Solid State CdWO4	Solid State CdWO4
Detector Configuration	32 x 2.0mm	32 x 2.0 mm
Spatial Resolution for Sharpest Clinical Algorithm ( <b>lp/cm at 2%</b> )	6.9	6.9
X-ray Tube Type	Rotating Anode	Rotating Anode
Heat Storage (MHU)	1.7	1.7
X-ray Tube Cooling	Liquid (50% Water, 50% Propylene Glycol)	Liquid (50% Water, 50% Propylene Glycol)
X-ray Fan Angle (deg)	45	45
Max X-ray Power (kW)	32	32
Rotating Speed (seconds)	2	2
Gantry Weight (kg)	1068	1068
Transfer of electric current	Data Dock system	Data Dock system

<b>Model Name</b>	<b>Airo® CT System (subject of this 510(k))</b>	<b>Airo® CT System (K131431)</b>
<b>Technological Characteristics</b>		
Mechanism to translate Gantry	Rails on Mobile Base System	Rails on Mobile Base System
Wireless	No	No
Mobile	Yes (motorized)	Yes (motorized)
Battery System	Yes (LiFePO4)	Yes (LiFePO4)
Wheels (casters)	Wheels (3 inch)	Wheels (3 inch)
Input Voltage	1 phase 100-240 volt	1 phase 100-240 volt
Input Power Max	1.5 kW	1.5 kW
PACS/DICOM 3.0	Yes	Yes
2D Scout	Yes	Yes
Bolus tracking	No	No
Dynamic Scan	No	No
Axial/Helical	<b>Axial and Helical</b>	Helical
Tube Modulation Feature	<b>Yes (Helical only)</b>	No
MPR	Yes	Yes
3D Viewing	No	No
Patient Table Option	Yes (Trumpf table column integrated with base)	Yes (Trumpf table column integrated with base)
Scan Motion	Scanner Moves	Scanner Moves
Laser Alignment	Patient Alignment	Patient Alignment
X-ray warning lights	Yes	Yes
110% X-ray Timer	Yes	Yes
Emergency Stop	Yes	Yes
Internal Lead Shield	Yes	Yes
External Lead Curtains	No	No
Operator X-ray On Switch	Yes	Yes
Quality Test Phantom	Yes	Yes

<b>Model Name</b>	<b>Airo® CT System (subject of this 510(k))</b>	<b>Airo® CT System (K131431)</b>
<b>Technological Characteristics</b>		
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
QA Test Report	Yes	Yes
Quality Test Phantom	Yes - Included	Yes - Included
Operating System	Microsoft Windows	Microsoft Windows
Biocompatibility	N/A	N/A
EM Emissions	ETL Testing	ETL Testing
Sterility	N/A	N/A
Chemical Safety	N/A	N/A
Thermal Safety	ETL Testing	ETL Testing
IEC EN 60601 Electrical Safety Testing	ETL Testing	ETL Testing
IEC EN 60601 Mechanical Safety Testing	ETL Testing	ETL Testing
Where Used	Mobile or Fixed Radiology, ICU, ED, Surgical, Clinic, Office	Mobile or Fixed Radiology, ICU, ED, Surgical, Clinic, Office
Anatomical Site	That which can be imaged in 51.2cm FOV and 107cm Aperture	That which can be imaged in 51.2cm FOV and 107cm Aperture

**7. General Safety and Effectiveness Concerns:**

Identical to its baseline 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 are certified to meet those requirements. Initial and Annual Reports are filed with the Center for Devices and Radiological Health (CDRH) according to 21 CFR 1002.10, 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 and National 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 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 and performance testing was performed to support substantial equivalence:

- Risk Analysis
- Design Reviews
- Design Verification Testing
- SW Unit Integration Testing
- System Software Verification & Validation Testing
- Image Quality Metrics
- Image Phantom Data
- Historical Clinical Image Data Reconstruction Comparison
- Offline Reconstruction Clinical Image Comparison (for NMAR feature)
- Independent Review Analysis for Diagnostic Image Quality
- Radiation/Dose Testing
- Electrical Safety, Mechanical & Stability Testing
- EMI/EMC Testing

The results of all testing performed indicate that the modified Airo CT System meets the acceptance criteria and is substantially equivalent to the currently cleared baseline device (Airo Mobile CT System - K131431).

#### **9. Conclusion:**

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