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

March 15, 2018

Re: K180393
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: February 12, 2018
Received: February 13, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K180393

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 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda. hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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@mobiusimaging.com

Date of Preparation: February 12, 2018

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 K160126 (cleared on April 19, 2016, 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 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 Gadolinium Oxysulfide (GOS) 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® is intended to be used for X-ray computed tomography applications for anatomy that can be imaged in the 107cm aperture excluding 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 (K160126, cleared on April 19, 2016) based on the following comparison. Most importantly, the differences noted below and in the comparison table raise no new issues of safety or effectiveness based on all testing performed and presented in this 510(k):

- Added pediatric scanning feature/protocols
- Updated software to include scanning capabilities at 80 and 100kV to support pediatrics
- Updated software to include age and height parameters to the system protocols
- Modified the Indications for Use Statement to remove pediatric restriction

Predicate Device Technological Comparison			
Company	**Mobius Imaging, LLC**	**Mobius Imaging, LLC**	
510(k) Number	**This 510(k)**	**K160126**	
Model Name	**Airo CT System**	**Airo CT System**	
Technological Characteristics			***Comparison***
Indications for Use	The AIRO is intended to be used for X-ray computed tomography applications for anatomy that can be imaged in the 107cm aperture excluding patients weighing over 400 lbs (182 kg). 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.	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). 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	Equivalent –Removal of pediatric restriction only. Battery of bench testing with phantom images presented in Section 18.
Product Classification Code	JAK	JAK	Identical
Aperture (cm)	107	107	Identical
Image Field of View (cm)	51.2	51.2	Identical
Detector Material	Gadolinium Oxysulfide (GOS)	Gadolinium Oxysulfide (GOS)	Identical
Detector Configuration	32 x 2.0mm	32 x 2.0 mm	Identical
Spatial Resolution for Sharpest Clinical Algorithm **(lp/cm at 2%)**	6.9	6.9	Identical
X-ray Tube Type	Rotating Anode	Rotating Anode	Identical
Heat Storage (MHU)	1.7	1.7	Identical
X-ray Tube Cooling	Liquid (50% Water, 50% Propylene Glycol)	Liquid (50% Water, 50% Propylene Glycol)	Identical
X-ray Fan Angle (deg)	45	45	Identical

Predicate Device Technological Comparison			
Company	**Mobius Imaging, LLC**	**Mobius Imaging, LLC**	
510(k) Number	**This 510(k)**	**K160126**	
Model Name	**Airo CT System**	**Airo CT System**	
Technological Characteristics			***Comparison***
Scanning capabilities (kV)	80, 100, 120 kV	120 kV (80 and 100 kV was not used)	Equivalent - SW change for Pediatrics– Battery of bench testing has been completed
Max X-ray Power (kW)	32	32	Identical
Rotating Speed (seconds)	2	2	Identical
Gantry Weight (kg)	1068	1068	Identical
Transfer of electric current	Data Dock system	Data Dock system	Identical
Mechanism to translate Gantry	Rails on Mobile Base System	Rails on Mobile Base System	Identical
Wireless	No	No	Identical
Mobile	Yes (motorized)	Yes (motorized)	Identical
Battery System	Yes (LiFePO4)	Yes (LiFePO4)	Identical
Wheels (casters)	Wheels (3 inch)	Wheels (3 inch)	Identical
Input Voltage	1 phase 100-240 volt	1 phase 100-240 volt	Identical
Input Power Max	1.5 kW	1.5 kW	Identical
PACS/DICOM 3.0	Yes	Yes	Identical
2D Scout	Yes	Yes	Identical
Bolus tracking	No	No	Identical
Dynamic Scan	No	No	Identical
Axial/Helical Modes	Axial and Helical	Axial and Helical	Identical
Tube Modulation Feature	Yes (Helical mode only)	Yes (Helical mode only)	Identical
MPR	Yes	Yes	Identical
3D Viewing	No	No	Identical
Patient Table	Yes (optional Trumpf table column integrated with base)	Yes (optional Trumpf table column integrated with base)	Identical

Predicate Device Technological Comparison			
Company	**Mobius Imaging, LLC**	**Mobius Imaging, LLC**	
510(k) Number	**This 510(k)**	**K160126**	
Model Name	**Airo CT System**	**Airo CT System**	
Technological Characteristics			***Comparison***
Scan Motion	Scanner Moves	Scanner Moves	Identical
Laser Alignment	Patient Alignment	Patient Alignment	Identical
Radiation Safeguards Hardware			
X-ray warning lights	Yes	Yes	Identical
110% X-ray Timer	Yes	Yes	Identical
Emergency Stop	Yes	Yes	Identical
Internal Lead Shield	Yes	Yes	Identical – Internal lead shield behind Detector for Collimated X-ray Beam and 1/2-inch aluminum Gantry housing for scatter shielding
External Lead Curtains	No	No	Identical
Operator X-ray on Switch	Yes	Yes	Identical
Quality Test Phantom	Yes	Yes	Identical
Radiation Safeguards Software			
Login ID/password	Yes	Yes	Identical
Administrator Privileges	Yes	Yes	Identical
Dose Display	Yes	Yes	Identical
Dose Report/Audit	Yes	Yes	Identical
Protocol Override Protection	Yes	Yes	Identical
Protocols by age, height, weight, and body region	Yes	No (weight/body region only)	Equivalent – SW 2.0 added age and height for Pediatrics - Battery of bench testing presented in Section 18.
QA Test Report	Yes	Yes	Identical
Quality Test Phantom	Yes	Yes	Identical

Predicate Device Technological Comparison			
Company	**Mobius Imaging, LLC**	**Mobius Imaging, LLC**	
510(k) Number	**This 510(k)**	**K160126**	
Model Name	**Airo CT System**	**Airo CT System**	
Technological Characteristics			***Comparison***
Operating System	Microsoft Windows	Microsoft Windows	Identical
Biocompatibility	N/A	N/A	Identical
EM Emissions	ETL Testing	ETL Testing	Identical
Sterility	N/A	N/A	Identical
Chemical Safety	N/A	N/A	Identical
Thermal Safety	ETL Testing	ETL Testing	Identical
IEC EN 60601 Electrical Safety Testing	ETL Testing	ETL Testing	Identical
IEC EN 60601 Mechanical Safety Testing	ETL Testing	ETL Testing	Identical
Can be used in	Mobile or Fixed Radiology, ICU, ED, Surgical, Clinic, office	Mobile or Fixed Radiology, ICU, ED, Surgical, Clinic, Office	Identical
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	Identical

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 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) + A1:2012 -** Medical electrical equipment Part 1: General requirements for basic safety and essential performance

- **IEC 60601-1-2:2007** - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

- **IEC 60601-1-3:2008 + A1:2013** - Medical electrical equipment – Part 1-3: General Requirements for basic safety and essential performance - Collateral Standard Radiation Protection in Diagnostic X-Ray Equipment

- **IEC 60601-1-6:2010 +A1:2013 -** Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- **IEC 60601-2-44:2009 + A1:2012 + A2:2016 -** Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

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

- **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 62133:2012 -** Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

- **IEC 62304:2006 +A1:2015 -** Medical device software – Software life cycle processes

- **IEC 62366:2007 + A1:2014** - Medical devices – Application of usability engineering to medical devices

- **NEMA XR 25-2010** - Computed Tomography Dose Check

- **NEMA XR 29-2013** - Standard Attributes on CT Equipment Related to Dose

In addition to the standards above, the following FDA Guidance Documents for pediatric use with medical devices and for Cybersecurity were referenced when preparing this 510(k):

- FDA Guidance for ***"Content of Premarket Submissions for Management of Cybersecurity in Medical Devices***" dated October 2, 2014
- FDA Guidance for "***Postmarket Management of Cybersecurity in Medical Devices*"** dated December 28, 2016
- FDA Guidance for **"*Pediatric Information for X-ray Imaging Device Premarket Notifications*"** dated November 28, 2017
- FDA Guidance for **"*Premarket Assessment of Pediatric Medical Devices*"** dated March 24, 2014

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 software modifications 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 and phantom images for Pediatrics
- Pediatrics Protocol Design & Validation (using Image Gently, ACR and AAPM guidelines)
- 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 – K160126).

9. Conclusion:

Based upon the above considerations, including all testing presented in this 510(k), 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.