GE Medical Systems, LLC
% Martha Kamrow, Ph.D.
Senior Regulatory Affairs Leader
3000 N. Grandview Blvd.
WAUKESHA WI 53188

April 28, 2021

Re: K210982
Trade/Device Name: AMX Navigate
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: March 31, 2021
Received: April 1, 2021

Dear Dr. Kamrow:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K210982

Device Name
AMX Navigate

Indications for Use *(Describe)*

The AMX Navigate is intended to take exposures utilizing film, computed radiography (CR), or wireless detectors, which are intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR).

AMX Navigate is a self-contained; battery operated mobile radiographic imaging system designed to generate diagnostic radiographic images (medical x-rays) that may increase the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. Medical x-rays are used in many types of examinations and procedures, some examples include: x-ray radiography (to find orthopedic damage, tumors, pneumonias, foreign objects).
The AMX Navigate is indicated for use on adult and pediatric patients for general-purpose diagnostic radiographic examinations and procedures. Its mobility enables general-purpose radiographic procedures throughout the clinical environment, or as needed within the emergency, intensive care, premature birth ward, cardiac and operating departments, for patients that may not be able to be moved or in cases where it is unsafe or impractical to move them to a traditional RAD room.

The system is indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts with the patient sitting, standing, or lying in the prone or supine position.

This device is not intended for mammographic applications.

The AMX Navigate incorporates AutoGrid, which is an optional image processing software installed as a part of the systems Helix image processing software. AutoGrid can be used in lieu of an anti-scatter grid to improve image contrast in general radiographic images by reducing the effects of scatter radiation.

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.

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## 510(k) Summary

K210982

In accordance with 21 CFR 807.92 the following summary of information is provided:

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| Date Submitted: | March 31 2021 |
| Submitter: | GE Medical Systems, LLC<br>3000 N. Grandview Blvd<br>Waukesha, WI 53188, USA |
| Primary Contact Person: | Martha Kamrow<br>Senior Regulatory Affairs Leader<br>GE Healthcare<br>262-548-2673<br>Martha.Kamrow@ge.com |
| Secondary Contact Person: | Diane Uriell<br>Regulatory Affairs Senior Director<br>GE Healthcare<br>262-290-8218<br>Diane.Uriell@ge.com |
| Device Trade Name: | AMX Navigate |
| Common/Usual Name: | Mobile X-ray system |
| Regulation, Classification, and Product Code: | Regulation Name: Mobile X-Ray System<br>Regulation: 21 CFR 892.1720<br>Classification: Class II<br>Product Codes: IZL, MQB |

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| Predicate Device(s): | Optima XR240amx with RFID (K182234)<br>Regulation Name: Mobile X-Ray System<br>Regulation: 21 CFR 892.1720<br>Classification: Class II<br>Product Codes: IZL, MQB |
| Device Description: | The AMX Navigate is intended to take exposures, using a wired or remote exposure switch, utilizing film, computed radiography (CR), or cleared wireless radiographic detectors, which are intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR).<br>AMX Navigate is a self-contained; battery operated mobile radiographic imaging system designed to generate diagnostic radiographic images (medical x-rays) that may increase the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. Medical x-rays are used in many types of examinations and procedures, some examples include x-ray radiography (to find orthopedic damage, tumors, pneumonias, foreign objects).<br>The AMX Navigate system is indicated for use on adult and pediatric patients for general-purpose diagnostic radiographic examinations and procedures. Its mobility enables general-purpose radiographic procedures throughout the clinical environment, or as needed within the emergency, intensive care, premature birth ward, cardiac and operating departments, for patients that may not be able to be moved or in cases where it is unsafe or impractical to move them to a traditional RAD room.<br>The incorporation of an optional collapsible column allows for improved workflow by delivering a less obstructed view when driving the system and includes a motion assist to reduce user efforts when driving the column vertically.<br>The system is indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts with the patient sitting, standing, or lying in the prone or supine position.<br>This device is not intended for mammographic applications. |
| Intended Use / Indications for Use: | The AMX Navigate is intended to take exposures utilizing film, computed radiography (CR), or wireless detectors, which are intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR).<br>AMX Navigate is a self-contained; battery operated mobile radiographic imaging system designed to generate diagnostic radiographic images |

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| | (medical x-rays) that may increase the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. Medical x-rays are used in many types of examinations and procedures, some examples include x-ray radiography (to find orthopedic damage, tumors, pneumonias, foreign objects).<br><br>The AMX Navigate is indicated for use on adult and pediatric patients for general-purpose diagnostic radiographic examinations and procedures. Its mobility enables general-purpose radiographic procedures throughout the clinical environment, or as needed within the emergency, intensive care, premature birth ward, cardiac and operating departments, for patients that may not be able to be moved or in cases where it is unsafe or impractical to move them to a traditional RAD room.<br><br>The system is indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts with the patient sitting, standing, or lying in the prone or supine position.<br><br>This device is not intended for mammographic applications.<br><br>The AMX Navigate incorporates AutoGrid, which is an optional image processing software installed as a part of the systems Helix image processing software. AutoGrid can be used in lieu of an anti-scatter grid to improve image contrast in general radiographic images by reducing the effects of scatter radiation. |
| Technology: | The AMX Navigate employs the same fundamental scientific technology as the predicate device. They are both battery operated mobile x-ray systems that capture exposures utilizing film, CR plates, or a wireless detector. The intended use is the same between the AMX Navigate and the predicate device. The AMX Navigate did not change the input power, battery subsystem, drive subsystem, x-ray generation, and exposure control from the predicate devices. The difference being introduced is a modification to the hardware and software to incorporate an optional collapsible column. The incorporation of an optional collapsible column allows for improved workflow by delivering a less obstructed view when driving the system and includes a motion assist to reduce user efforts when driving the column vertically. The hardware on the AMX Navigate has been modified to include the optional collapsible column and a horizontal arm assembly to provide a longer travel range for the tube/collimator. The software on the AMX Navigate has been modified to support the optional collapsible column and improves the algorithm for previewing images and image processing |
| Determination of Substantial Equivalence: | <u>Summary of Non-Clinical Tests:</u><br><br>The following quality assurance measures were applied to the development of the AMX Navigate system: |

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| | ▪ Risk Analysis<br>▪ Requirements Reviews<br>▪ Design Reviews<br>▪ Testing on unit level (Module verification)<br>▪ Integration testing (System verification)<br>▪ Performance testing (Verification)<br>▪ Safety testing (Verification)<br>▪ Simulated use testing (Validation)<br><br>New risks were identified for incorporating the optional collapsible column and associated software into the AMX Navigate. These risks were reviewed and mitigated with design controls and labeling. The mitigations were verified and validated as a part of the design verification and validation testing that has been executed with acceptable results.<br><br><u>Summary of Clinical Tests:</u><br><br>The subject of this premarket submission, AMX Navigate, did not require clinical studies to support substantial equivalence of incorporating an optional collapsible column.<br><br>Design verification and validation testing was performed to confirm that the safety and effectiveness of the device has not been affected. The test plans and results have been executed with acceptable results. |
| Conclusion: | The AMX Navigate incorporates an optional collapsible column allowing for improved workflow by delivering a less obstructed view when driving the system and includes a motion assist to reduce user efforts when driving the column vertically. This update to this system does not result in any new potential safety risks, it has the same technological characteristics, and perform as well as the devices currently on the market.<br><br>After analyzing design verification and validation testing on the bench it is the conclusion of GE Healthcare that the AMX Navigate to be as safe, as effective, and performance is substantially equivalent to the predicate devices. |