December 13, 2021

Omega Medical Imaging, LLC
% Mr. John Newman
Regulatory Specialist
3400 St. Johns Parkway, Suite 1020
SANFORD FL 32771

Re: K212890
Trade/Device Name: Nyquist.IQ
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified Fluoroscopic X-ray System
Regulatory Class: Class II
Product Code: JAA, MQB
Dated: November 10, 2021
Received: November 12, 2021

Dear John Newman:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212890

Device Name
Nyquist.IQ

Indications for Use *(Describe)*
The Omega Medical Imaging, LLC Nyquist.IQ Image Processor is intended for use in Radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging. The Nyquist.IQ is intended solely to be integrated only with Omega Medical Imaging CS-series-FP Systems.

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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Traditional 510(k) SUMMARY

K212890

Company Name:	Omega Medical Imaging, LLC
Address:	3400 St. Johns Parkway, Suite 1020, Sanford, Fl 32771
Telephone No:	407-323-9400
Registration No:	1052701
Contact person:	John Newman (Regulatory Affairs Specialist)
Date Prepared:	09/02/2021
Device (trade) name:	Nyquist.IQ
Common/usual name:	Image Processor
Classification Name:	Image Processor
Classification Panel:	Radiology
CFR section:	892.1650
Device Class:	Class II
Primary Product code:	JAA
Secondary product code:	MQB

Predicate Device K182834

Company Name:	Omega Medical Imaging, LLC
Address:	3400 St. Johns Parkway, Suite 1020
Telephone No:	407-323-9400
Registration No:	1052701
Contact person:	John Newman
Date Prepared:	03/29/2019
Device (trade) name:	CS-series-FP with Optional Accessory Device CA-100S (FluoroShield)
Common/usual name:	Fluoroscopic/Radiographic X-ray system
Classification Name:	System, X-Ray, Fluoroscopic, Image -Intensified
Classification Panel:	Radiology
CFR section:	892.1650
Device Class:	Class II
Primary Product code:	JAA
Secondary Product code:	OWB

Reference Predicate Device K121293

Company Name:	Omega Medical Imaging, LLC
Address:	675 Hickman Circle, Sanford, Fl 32771
Telephone No:	407-323-9400
Registration No:	1052701
Contact person:	John Newman
Date Prepared:	04/20/2012
Device (trade) name:	CS-series-FP with 3030+ Option
Common/usual name:	Fluoroscopic/Radiographic X-ray system
Classification Name:	System, X-Ray, Fluoroscopic, Image -Intensified
Classification Panel:	Radiology
CFR section:	892.1650
Device Class:	Class II
Primary Product codes:	JAA
Secondary Product code:	OWB

Indication of use:

The Omega Medical Imaging, LLC Nyquist.IQ IP-100 Image Processor is intended for Radiographic/fluoroscopic applications including cardiac, vascular, g diagnostic, and interventional x-ray imaging.

The Nyquist.IQ is intended solely with the Omega Medical Imaging CS-series-FP system.

Device description:

Nyquist.IQ is a dynamic digital imaging processing system. The system application is based on a operating system functioning on a PC based CPU. The embedded software performs real-time image processing and full storage. The DICOM compliant connectivity provi patient demographics, examination, and image data digitally.

Nyquist.IQ is not a standalone device, but functions as a component for the CS-series-FP platform. Nyquist IQ is an image processor to acquire and digitize x-ray exposure from the Omega medical CS-series-FP.

The Nyquist.IQ operates in connection with the Varex s 3030+ or the T This is demonstrated in the substantial equivalence. The Nyquist.IQ is intended solely for the Omega CS-series-FP with Optional Accessory IS-1000 FluoroShield platform.

The Nyquist.IQ is intended solely with Canon Medical Imaging-FP CS systems.

The Nyquist.IQ image processor. The fundamental performance of the Nyquist.IQ interventional fluoroscopic imaging Processor consists of:

- Real-time image visualization of patient anatomy during procedures
- Imaging techniques and tools to assist interventional procedure[s]
- Post-processing functions after interventional procedures.
- Storage of reference/control images for patient records.
- Compatibility to images of other modalities via DICOM
- Compatibility with the already FDA cleared CA100S / FluoroShield AI Exposure Reduction Technology (K182834)

This array of functions provides the physician the imaging informatio[n] ... invasive interventional procedures.

The Nyquist.IQ image processor is available as P-500 Model configuration and is similar to ... marketed and predicate image processor P-200 MS Series-FP with optional CA100S / FluoroShield Device.

Patient Population

General Population, additional concerns must be taken for pediatric use.

Based on the information provided above, the Nyquist.IQ system is considered substantially e... the current marketed predicate device P-200 MS Series-FP with optional CA100S / FluoroShield Device. Both share the same indications for use.

Technological characteristics

The Nyquist.IQ system has similar technological characteristics compared t... improvements to it. Below are the key improvements between the Nyquist.IQ image processor and the predicate device.

- Integration of a New Flat Panel Detector (Teledyne Xineos) ... with the already FDA cleared FluoroShield AI Exposure Reduction Technolog...

The difference between the Nyquist.IQ system and the predicate device does not rais... regarding safety or effectiveness. Based on the information provided in this 510K s... Nyquist.IQ is considered substantially equivalent to the currently marketed P-200 MS Series-FP with optional CA100S / FluoroShield Device in terms of fundamental technology

Summary of Non-Clinical Performance

Non-clinical performance testing has been performed on the Nyquist.IQ Image processor and demonstrated compliance with the following International and FDA approved conse
documents:

1. IEC 62304 Medical device software – Software life cycle processes (Edition 1.1, 2015-06). FDA/CDRH recognition number 13-79
2. ISO 14971 Medical devices – Application of risk management to medical devic… -03-01). FDA/CDRH recognition number 5-40.
3. Guidance for Industry and FDA Staff – Guidance for the Content of premarket Subm… Software Contained in Medical Devices, May 11, 2005 (document number 337).
4. Guidance for Industry and FDA Staff – The 510(k) Program: Evaluating Substantia… Premarket Notifications [510(k)], July 28, 2014 (document numbe…

Software verification testing on the functional requirements, as well as p… reliability, and safety, have been performed to verify that all conditi… Specifications, as well as the safety risk control measures from the … privacy and security requirements, have been implemented. Results demonstrated executed verification test was passed.

Non-clinical validation testing has been performed to validate that the Nyquist.IQ Image Processor … conforms to the intended use, users, and claims, service needs, effectively satisfying … instruction for use.

The Nyquist.IQ did not require clinical study data since substantial equivalen… predicate device Omega CS-FER with Optional Accessory CA-100S / FluoroShield was demonstrated with the following attributes:

- Indication for use.
- Technological characteristics.
- Non-clinical performance testing; and
- Safety and effectiveness.

Substantial equivalence Conclusion:

The Nyquist.IQ system is substantially equivalent to the currently marketed device CS-FER with the Optional Accessory CA-100S / FluoroShield in terms of indications for use, techno… characteristics, safety and effectiveness.

The Nyquist.IQ Image Processor works within the controls and predetermined specifica… Additionally, substantial equivalence was demonstrated by non-clinical performance testing provided in this 510(k) premarket notification. These tests demonstrate that the Nyquist.IQ system complies with the use… requirements and the requirements specified in the FDA-recognized consensus standards and… documents.

Therefore, Nyquist.IQ is as safe and effective as its predicate device and doe… and/or effectiveness concerns.

Comparison with Predicate Devices:

	Indications for use comparison:		
510(k) Number and Device Name	K121293 (Ref. Predicate Device) CS-series-FP with 3030+ option	K182834 (Predicate Device) CS-series-FP with Optional Accessory Device CA-100S / FluoroShield	(This Submission) Nyquist.IQ
Intended Use	The Omega Medical Imaging, LLC CS-series-FP with 3030+ Option systems are intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional X-Ray imaging.	The Omega Medical Imaging, LLC CS-series-FP (SSXI) systems with optional accessory device CA-100S as a modification device to provide an automated Region of interest that manages exposure to the patient and operator. The system is intended for use in Radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/ fluoroscopic diagnostic, and interventional x-ray imaging for General Populations. At no time will the CA-100S be considered as a replacement for the primary collimator. The primary collimator shall always be used, in accordance with good medical practice, to define a Region of Interest	The Omega Medical Imaging, LLC IPS-100, Nyquist.IQ Image Processor is intended for use in Radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional X-Ray imaging. (The Nyquist.IQ is intended solely to be integrated only with Omega Medical Imaging CS-series-FP systems.)
Classification Name:	Image-intensified Fluoroscopic X-ray system	Image-intensified Fluoroscopic X-ray system	Image-intensified Fluoroscopic X-ray system
CFR Regulation #:	892.1650	892.1650	892.1650
Device Class	Class II	Class II	Class II
Classification Product Code:	JAA, OWB	JAA, OWB	JAA, MQB

PRODUCT OVERVIEW

Substantial Equivalence:

Detailed in the Bench testing section of this submission.

Safety information:

- The Omega Nyquist.IQ Image Processor complies with the applicable requirements of 21 CFR 820.
- The Omega Nyquist.IQ Image Processor complies with the international safety standards IEC 60601-1, IEC 60601-1-2, EN ISO 15223-1 and EN ISO 14971.
- The Omega Nyquist.IQ Image Processor systems comply with UL 60601-1 and CAN/CSA C22.2 No M90.
- The device is designed and manufactured under the Quality System Regulations 21 CFR 820 and ISO 13485 Standards. This device is in conformance with IEC 60601-1 standards and its collateral standards. All requirements of the F… as outlined in 21 CFR § 1020, that apply to this device will be met and…

Safety is assured through a risk management process and manufactu System Regulations.

Referenced Guidance Documents:

- Guidance for this submission of 510(k) for Indications of use as provided in: Pediatric Information for X-ray Imaging Device Premarket Notifications (Document issued on November 28th, 2017) Guidance for Industry and Food and Drug Administration Staff.
- Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices . (Document issued on October 2018)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Document issued on May 11, 2005)
- Guidance for Industry and FDA Staff: Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically -powered Medical Devices. (Document issued on July11, 2016)
- Guidance for this submission of 510(k) for (SSXID) Solid State X -ray Imaging Devices issued on: September 1, 2016 was used to establish substantial equivalence
- Guidance for industry and FDA Staff - User Fees and Refunds for Premarket Notification Submissions 510(k)s, (Document issued on October 2, 2017)
- Guidance for industry and FDA Staff - Refuse to A ccept Policy for 510(k) (Document issued on September 2019)
- Guidance for industry and FDA Staff -Format for Traditional and Abbreviated 510(k)s (Document issued on September 2019)
- Guidance for industry and FDA Staff - Deciding when to submit a 510(k) for a change to an existing device. (Document issued on October 25, 2017)
- Guidance for industry and FDA Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (Document Issued on July 28, 2014)
- Guidance for industry and FDA Staff - Guidance for Off -The-Shelf Software Use in Medical Devices (Document issued on September 2019)
- Guidance for industry and FDA Staff - Guidance for the Content of Premarket Submission for Software in Medical Devices. (Document issued May 11th, 2005)
- Guidance for industry and Food and Drug Administration Staff - Policy Clarification for Certain Fluoroscopic Equipment Requirements (Document issued on May 8, 2019)
- Guidance for Industry and FDA Staff - Medical X -Ray Imaging Devices Conformance with IEC Standards. (Document issued on May 8,2019)
- Guidance for Industry and FDA Staff - Clarification of Radiation Control Regulations for Manufacturers of Diagnostic X -Ray Equipment. (Document issued on December 17, 2018)
- Guidance for Industry and FDA Staff - Guidance for the submission of 510(k)s for Solid state X -ray Imagin g Devices. (Document issued on September 1, 2016)