March 18, 2024

Ionic Health
℅ Jay Mansour
Industry Consultant- The FDA Group
The FDA Group, LLC
290 Turnpike Road
Suite 200
Westborough, Massachusetts 01581

Re: K233660
Trade/Device Name: nCommand Lite System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, JAK, LNH, KPS
Dated: November 13, 2023
Received: November 15, 2023

Dear Jay Mansour:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Gabriela M. Rodal -S

Digitally signed by Gabriela M. Rodal -S

for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233660

Device Name

nCommand Lite System

Indications for Use *(Describe)*

The nCommand Lite system allows remote access for viewing/review of images as well as the ability to remotely provide real-time guidance to the licensed technologist operating a compatible MRI, CT, and PET-CT scanner. This access must be granted by the local licensed technologist operating the system. The remote access is only available for systems supporting remote connectivity capability. Images reviewed remotely are not for diagnostic use.

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

Prepared on: 2023-11-17

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	nCommand Lite System
Common Name	System, Image Processing, Radiological
Classification Name	Medical image management and processing system
Regulation Number	892.2050
Product Code	LLZ (primary) ; Secondary Product Codes: LNH, JAK,KPS)

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K150193	Customer Remote Console (CRC)	LLZ
K052423	MAGNETOM Systems with syngo Expert-i option	LNH
K061449	Syngo Expert-i	JAK

Device Description Summary

21 CFR 807.92(a)(4)

The nCommand Lite system is a SaMD (Software as Medical Device) that is customer-facing and provides remote access through a web application for viewing/reviewing images as well as the ability to remotely provide real-time guidance to the near-patient licensed technologist (local users) operating the medical imaging devices in the context of training, procedure assessment, for MRI, CT, and PET-

CT scanner.
Remote users are licensed technologists and are able to access an imaging medical device from a computer that meets the minimum required specifications anywhere, using a secure software connection that streams video and provides keyboard and mouse access. This allows remote users to assist local users, with both remote and local users' qualifications and responsibilities being subject to local regulations where the imaging occurs. This access must be granted by the local user using the system, and it can also be revoked at any time by the local user, thus allowing him/her to maintain complete control of the session at all times. Also, each remote session is controlled via a secure credential that is managed by the local user. Connections to a medical device are limited to one remote session at a time to maintain strict control over who is remotely interacting with the system. Images reviewed remotely are not for diagnostic use.
nCommand Lite is an IT hardware and software-based installation solution that supports multisession, allowing remote technologists to view multiple medical imaging devices as needed. However, access is restricted to one medical imaging device at any given time, as only one keyboard and one mouse are provided.
Scanners that are compatible with nCommand Lite system comply with a common protocol, allowing for scanning parameter management and remote scanning.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The nCommand Lite system allows remote access for viewing/review of images as well as the ability to remotely provide real-time guidance to the licensed technologist operating a compatible
MRI, CT, and PET-CT scanner. This access must be granted by the local licensed technologist operating the system. The remote access is only available for systems supporting remote connectivity capability. Images reviewed remotely are not for diagnostic use.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The rationale below includes (1) a general description of the conditions that the device will mitigate, including a description of the patient population for which the device is intended.
It also includes an explanation as to (2a) why the differences in the indications for use with predicate devices are not critical to the intended use of the device, (2b) why these differences do not constitute a new intended use of the device, and (2c) why these differences do not affect the safety and effectiveness of the device when used as labeled. Paragraphs (1) and (2) below cover the above.
(1) General description of the conditions and patient population of the device:
The nCommand Lite system is a SaMD (Software as Medical Device) that is customer-facing and provides remote access through a web application for viewing/reviewing images as well as the ability to remotely provide real-time guidance to the near-patient licensed technologist (local users) operating the medical imaging devices in the context of training, procedure assessment, for MRI, CT, and PET-CT scanner.
Remote users are licensed technologists and are able to access an imaging medical device from a computer that meets the minimum required specifications anywhere, using a secure software connection that streams video and provides keyboard and mouse access. This allows remote users to assist local users, with both remote and local users' qualifications and responsibilities being subject to local regulations where the imaging occurs. This access must be granted by the local user using the system, and it can also be revoked at any time by the local user, thus allowing him/her to maintain complete control of the session at all times. Also, each remote session is controlled via a secure credential that is managed by the local user. Connections to a medical device are limited to one remote session at a time to maintain strict control over who is remotely interacting with the system. Images reviewed remotely are not for diagnostic use.
nCommand Lite is an IT hardware and software-based installation solution that supports multisession, allowing remote technologists to view multiple medical imaging devices as needed. However, access is restricted to one medical imaging device at any given time, as only one keyboard and one mouse are provided.
Scanners that are compatible with nCommand Lite system comply with a common protocol, allowing for scanning parameter management and remote scanning.
(2) The intended use of the subject device and the primary predicate device [Customer Remote Console (CRC)] are identical. The indications for use of the subject device and the primary predicate device are also identical, except for the generalization from "GE Healthcare medical imaging devices" to "compatible MRI, CT, and PET-CT scanner". This generalization is achieved via the use of eKVM software and the hardware connectivity, all tested and validated.
The intended use of the subject device and the second predicate device [MAGNETOM Systems with syngo Expert-i option] are identical in intent, although the wording somewhat differs. Such differences do not change the fact that both achieve the same main purpose. Similarly, the indications for use of the subject device and the second predicate device are also identical, in that both allow for a remote technologist to assist a local technologist, except for the generalization from MRI scanners manufactured by Siemens Medical Solutions, to "compatible MRI, CT, and PET-CT scanner". This generalization is achieved via the use of eKVM software and the hardware connectivity, all tested and validated.
The intended use of the subject device and the third predicate device [Syngo Expert-i] are identical in intent, although the wording somewhat differs. Such differences do not change the fact that both achieve the same main purpose. Similarly, the indications for use of the subject device and the third predicate device are also identical, in that both allow for a remote technologist to assist a local technologist, except for the generalization from Syngo CT manufactured by Siemens Medical Solutions, Inc. USA, to "compatible MRI, CT, and PET-CT scanner". This generalization is achieved via the use of eKVM software and the hardware connectivity, all tested and validated.
The intended use and indications for use of the subject device and the fourth predicate device [Precision DL] are different, and this

device is rather used as REFERENCE device. This reference device is included as an added justification for the use of product code KPS to the subject device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device has different technological characteristics from the predicate device(s), for which a summary [of how the technological characteristics of the device compare to predicate devices] is detailed below.
The predicate devices are K150193 (primary), K052423 (second), K061449 (third) and K223212 (fourth/reference).
The subject device and all predicate devices have the following technological characteristics in common:
1- Customer Facing User Interface (UI).
2- Do not use Bluetooth or Wireless.
3- The use of Ethernet Wire Connection.
4- Software solution.
5- Not for Diagnostic Purpose
Excluding the fourth/reference predicate device, the subject device and predicate devices (primary, second and third) have the following technological characteristics in common:
1- Remote Access for viewing/reviewing images.
2- Provide real-time training to the licensed local technologist operating the scanner.
3- Access is granted to the remote technologist by the local technologist.
Remote Technologist works under the supervision of the local technologist, who can revoke the access permission of the remote technologist at any time.
4- Only one remote access per machine at any given time.
5- Parameter Management.
6- No Image Manipulation.
Excluding the primary predicate device and the fourth/reference device, the subject device and the predicate devices (i.e., second and third) have the following technological characteristics in common:
1- Remote Scanning
2- Provide real-time guidance to the licensed local technologist operating the scanner. This guidance includes procedure assessment, and scanning parameter management.
3- Ability of the remote technologist to open multiple sessions concurrently.
4- No Video Conferencing.
5- Chat Functionality.
The subject device and the primary predicate device have the following technological characteristics in common:
1- Web Browser Application.
The subject device has the following technological characteristics that are not in common with ANY of the 4 predicate devices:
1- Connected machines are MRI, CT, and PET-CT, while:
a. Primary predicate device connects only with GEHC imaging* medical device [*This includes MRI, CT, and PET-CT]
b. The second predicate device connects only with MRI machines from Siemens Medical Solutions (MAGNETOM Systems with syngo Expert-i option).
c. The third predicate device connects only with CT machines from Siemens Medical Solutions, Inc. USA.
d. The fourth/reference device connects only with PET-CT machines from GE Healthcare.
2- Connected devices are not machine brand specific, while:
a. Primary predicate device connects only with GEHC imaging* medical device [*This includes MRI, CT, and PET-CT]
b. The second predicate device connects only with MRI machines from Siemens Medical Solutions (MAGNETOM Systems with syngo Expert-i option).
c. The third predicate device connects only with CT machines from Siemens Medical Solutions, Inc. USA.
d. The fourth/reference device connects only with PET-CT machines from GE Healthcare.
3- Recognized standards are different, as justified elsewhere in detail. Although technological characteristics are in common with some or all of the predicate devices, the underlaying architectural solution of the subject device is different, forcing a different set of recognized standards to apply to it.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Nonclinical tests include (1) software testing, (2) cybersecurity testing and (3) usability engineering / human factors testing.
The FDA guidance documents that were followed are:
1- Content of Premarket Submissions for Device Software Functions. Guidance for Industry and Food and Drug Administration Staff. JUNE 2023
2- Software as a Medical Device (SAMD): Clinical Evaluation Guidance for Industry and Food and Drug Administration Staff. DECEMBER 2017
3- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Guidance for Industry andFood and Drug Administration Staff. Document issued on September 27, 2023

4- General Principles of Software Validation Guidance for Industry and FDA Staff. JANUARY 2002

5- Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff. FEBRUARY 2016

The recognized standards that were followed are:

1- ISO 14971:2019 - Medical devices — Application of risk management to medical devices. Recognition number: 5-125

2- IEC 62304:2006/Amd 1:2015 - Medical device software — Software life cycle processes — Amendment 1. Recognition number: 13-79

3- ANSI/AAMI SW91:2018 - Classification Of Defects In Health Software. Recognition number:13-105

4- NIST Cybersecurity Framework - Version: 1.1, Date April 16, 2018. Recognition number: 13-118

5- Medical Device and Health IT Joint Security (JSP) - Jan 2019 IEC 81001-5-1:2021. Recognition number: 13-122

6- ANSI/ISA 62443-4-1 Version: 2018, Date: February 2018 - Security for industrial automation and control systems Part 4-1. Recognition number: 13-119

7- AAMI TIR57 Version: 2016, Date:2016 - Principles for medical device security - Risk Management. Recognition number: 13-83

8- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices. Recognition number: 5-129

9- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and Supportive Publication section below. Recognition number: 19-49

10- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. Recognition number: 19-36

The conclusion drawn from the non-clinical tests demonstrates that the subject device in this 510(k) submission, nCommand Lite System, is as safe, as effective, and performs equivalently to the legally marketed predicate devices.