March 1, 2023

Noah Medical Corp.
Sam Mostafavi
Regulatory Affairs
1501 Industrial Rd.
San Carlos, California 94070

Re: K223144
Trade/Device Name: Galaxy System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: January 27, 2023
Received: January 27, 2023

Dear Sam Mostafavi:

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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)*
K223144

Device Name
Galaxy System

Indications for Use *(Describe)*

The Galaxy System and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic 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.***

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# 510(k) Summary

This summary of 510(k) for information regarding substantial equivalency is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**510(k) Number:** K223144

**Applicant Information:**


| | |
|---|---|
| Date Prepared: | November 15, 2022 |
| Manufacturer: | Noah Medical Corp.<br>1501 Industrial Rd.<br>San Carlos, CA 94070 |
| Contact Person: | Sam Mostafavi<br>sammostafavi@noahmed.com |
| Mobile Number: | 650-670-6972 |
| Fax: | 650-578-9653 |


**Device Information:**

| | |
|---|---|
| Trade/Device Name: | Galaxy System |
| Regulation Number: | 21 CFR § 874.4680 |
| Regulation Name: | Bronchoscope (Flexible or Rigid) and Accessories |
| Regulatory Class: | Class II |
| Product Code | EOQ |
| Panel: | Ear, Nose, and Throat Devices |

**Device Description**

The Galaxy System is designed with the intent to enable articulation and precise control of a flexible, single-use disposable bronchoscope under continuous and direct control by a physician operator. The Galaxy System™ includes full procedure navigation that integrates a pre-operative computed tomography scan to display scope tip location relative to the pre-operative scan anatomy. Additionally, Galaxy integrates a tomosynthesis spin to update the scope and target position to overcome any changes in anatomy not reflected in the pre-op CT scan.

**Intended use/Indications for use**

The Galaxy System and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.

**Primary Predicate Device:**

- K173760, Auris Surgical, Monarch Endoscopy Platform

**Reference Device:**

- K173244, Covidien, Super Dimension Navigation System

## Comparison of Technological Characteristics with the Predicate and Reference Device

Overall, the Galaxy System and the Monarch Platform (Predicate Device) are based on the following basic technological elements:

- Both systems contain a flexible bronchoscope to visualize and gain access to patient airways
- Both systems are intended for diagnostic and therapeutic procedures performed by physicians using tools inserted through the bronchoscope working channel.
- Both systems require continuous direct control by a physician to move the bronchoscope.
- Both systems move the distal tip of the bronchoscope by moving pull wires.
- Both systems utilize a bronchoscope that is provided sterile or is sterilized prior to procedure

The Galaxy System enables a physician to utilize electro-mechanical articulation for precise control of a flexible endoscope (bronchoscope) under continuous camera visualization. A pre-operative computed tomography (CT) scan of the patient is imported into the proprietary Galaxy Planning System, which provides a 3D virtual image of the patient airways to the physician operator. By utilizing electromagnetic field-based sensors on the tip of the endoscope, the endoscope tip location relative to the pre-operative scan anatomy is continuously displayed. This technology is equivalent to the technology used in the Auris Surgical Monarch Platform, which also uses electro-mechanical articulation, pre-op CT scan data, and electromagnetic navigation.

The navigation subsystem used by the Galaxy System utilizes the same electromagnetic navigation technology as the predicate and reference devices. It uses the same equivalent off-the-shelf EM navigation hardware (same manufacturer) as the primary predicate. Galaxy involves a similar registration process by driving to main airways in both lungs as both predicate and reference devices. It also provides similar navigation views (e.g., virtual endoluminal view, virtual global view, targeting view and CT views) as the predicate and reference devices

The Galaxy System includes optional generation of a partial 3D reconstruction of the lung through TiLT (tool in lesion tomography) Technology to compensate for CT-to-body divergence through incorporation of additional fluoroscopic imaging data taken during the electromagnetic navigation procedure. This is similar to the technology used in the superDimension™ Navigation (Reference Device) system which also uses tomography to compensate for CT-to-body divergence, prior to the biopsy.

For these reasons, we are using the cleared Auris Surgical Monarch Platform (K173760), and Covidien superDimension™ Navigation System (K173244) as the predicate and reference devices, respectively

## Performance Data

The Galaxy System has been successfully tested for installation, function, performance, and safety per FDA-recognized standards. Additionally, the Galaxy System has been evaluated for electrical safety, electromagnetic compatibility, biocompatibility, and toxicity testing of patient-contacting materials. The following performance data is provided in support of the substantial equivalence determination.

- **Biocompatibility testing**

  The biocompatibility evaluation for the direct and indirect body contacting components of the Galaxy System, specifically the Galaxy Bronchoscope and Galaxy single-use accessories were conducted in accordance with the International Standard ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by the FDA.

  The Ethylene Oxide sterilized devices were validated as biocompatible with the appropriate selection of tests indicated for Externally Communicating Devices, in contact with Tissue/Bone/Dentin, with limited contact duration (less than 24 hours). Tests included Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity and Material-Mediated Pyrogenicity

- **Electrical safety and electromagnetic compatibility (EMC)**

  Electrical safety and EMC testing were conducted on the Galaxy System, including Galaxy Bronchoscope System and Cart. The system complies with the applicable requirements of IEC 60601-1:2005, AMD1:2012, IEC 60601-1-6:2010 +AMD1:2013, IEC 60601-2-18:2009, and the IEC 60601-1-2:2020 standard.

- **Software Verification and Validation Testing**

  Galaxy System software verification and validation testing were conducted and supporting documentation are provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005. Results of verification and validation testing confirm that Galaxy System software conforms to the design specifications and meets the intended use and needs of the intended users.

- **Performance Testing**

  - Dimensional Testing
  - Mechanical Verification
  - Functional Verification
  - Tools Compatibility Testing
  - Sterilization Validation
  - Cleaning Compatibility
  - Packaging and Shelf Life
  - Cybersecurity Testing
  - Shipping and Transit Testing
  - Usability Testing
  - Simulated Use

- **Animal and Cadaver Testing**

  Noah performed Design Validation testing in human cadaver and animal models to validate that Galaxy System meets user needs during a simulated use bronchoscopy procedure by the intended users for the intended uses and under the expected use conditions.

- **Human Factor Usability Testing**

  Noah performed cadaver and animal testing in accordance with "AAMI HE75:2009 Human Factors Engineering - Design of Medical Devices, Section 9 – Usability Testing", to demonstrate that the Galaxy system design meets the intended user needs and is substantially equivalent to the predicate device. Simulated testing by representative users demonstrated that Galaxy System design meets the intended user requirements and facilitates user interactions with little chance of committing dangerous and unacceptable user errors.

Dimensional, mechanical, and functional testing confirms that the Galaxy bronchoscope and predicate scope are substantially equivalent, having the same mechanical operating principles and similar dimensions. Performance testing was completed with the Olympus bronchoscope, used by the predicate device as well. Noah performed Design Validation testing in human cadaver and animal models to validate the Galaxy System with and the corresponding training for safety and effective use during a simulated use of bronchoscopy procedures by the intended users for the intended uses and under the expected use conditions. The simulated use of bronchoscopy procedures evaluates the functionality and performance of the Galaxy System's bronchoscope, electromagnetic navigation, and optional tomosynthesis features in order to successfully navigate to a peripheral lung lesion and acquire a biopsy of the lesion. Specifically, the evaluation confirmed users' ability to navigate to within 30 mm of the lesion, complete tomosynthesis, and acquire tissue with an off-the-shelf biopsy instrument through the working channel. At the end of the simulated use bronchoscopy procedure, users confirmed the bronchoscope driving was smooth and responsive with minimal latency, the overall system provides repeatable and

consistent performance, and that the bronchoscope was able to reach central and peripheral areas of the lung. The user group included physicians who have been trained and are actively using the predicate and reference devices.

## Conclusion:

Based on the technological characteristics and performance testing, it is determined that the subject device, Galaxy System, is substantially equivalent to the predicate device. Therefore, it is the conclusion of Noah Medical that Galaxy system is substantially equivalent to the cited predicate device (Monarch Endoscopy Platform (K173760)) on the general intended use.