DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993 0002

September 19, 2014

Nemaris, Inc.
% Mr. Keith Barritt
Attorney
Fish and Richardson P.C.
1425 K Street NW
WASHINGTON DC 20005

Re: K141669
Trade/Device Name: Surgimap 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 13, 2014
Received: August 14, 2014

Dear Mr. Barritt:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
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)*
K141669

Device Name
Surgimap

Indications for Use *(Describe)*
The Surgimap software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The device allows service providers to perform generic as well as specialty measurements of the images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants, and offer online synchronization of the database with the possibility to share data among Surgimap users. Clinical judgment and experience are required to properly use the software.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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"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 of Safety and Effectiveness
Nemaris Inc.
Surgimap

The following information is provided pursuant to 21 CFR 807.92

807.92(a)(1)

(i) Submitter

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(ii) Submitter Contact

Virginie Lafage, PhD
Vice President and Chief Technology Officer
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New York, NY 10003
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(iii) Preparation Date

May 05, 2014

807.92(a)(2)

Trade Name	Surgimap
Common Name:	Picture Archiving and Communication System (PACS)
Section:	892.2050
Class	II
Product Code:	LLZ

807.92(a)(3)

- Surgimap Spine
  - Manufacturer: Nemaris Inc
  - Tradename: Surgimap Spine
  - 510K #: K111019 (September 30, 2011)
  - Common Name Picture Archiving and Communication System (PACS)
  - Class: II
  - Product Code: LLZ
- Traumacad
  - Manufacturer: Voyant Health formerly known as Orthocrat
  - Tradename: TraumaCad Release 2.0
  - 510K #: K073714 (March 19, 2008)
  - Common Name Picture Archiving and Communication System (PACS)
  - Class: II
  - Product Code: LLZ

807.92(a)(4)

Surgimap is software developed for the medical community. It is intended to be used to view, store and transport images as well as perform generic or specialty measurements and plan or simulate aspects of surgical procedures. The image formats supported encompasses the standard image formats (jpeg, tiff, png, ….) and also DICOM images. Images can be stored in the Surgimap database and measurements (generic or specialty specific) can be overlaid to each image. Surgimap also offers the ability for the end user to plan, or simulate, aspects of certain surgical procedures such as osteotomies and templating implants (including but not limited to screws, interbody cages, rods). Via internet connection during use of the software application, the database can be synchronized online. An optional feature consists in organizing patient information into cases with the possibility to share these cases among Surgimap users.

807.92(a)(5)

The Surgimap software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The device allows service providers to perform generic as well as specialty measurements of the images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants, and offer online synchronization of the database with the possibility to share data among Surgimap users. Clinical judgment and experience are required to properly use the software.

The Indications for Use statement for Surgimap 2.0 device is not identical to the predicate devices; however, the differences do not affect the safety and effectiveness of the device relative to the predicates. The subject and predicate devices have the same intended use for local images, and in both cases, the mitigation of hazard analysis demonstrates an acceptable level of residual risks.

807.92(a)(6)

The tabulated comparison of technological characteristics between Surgimap Spine and its predicated devices is outlined in the table hereafter:

Feature	TraumaCad 2.0	Surgimap Spine	Surgimap 2.0
Computer	PC Compatible	PC Compatible	PC Compatible
Operating System	Windows	Windows	Windows + MAC
Image Input	Local + PACS connectivity	Local	Local + PACS connectivity
Scout feature	Yes	No	Yes
Runs on Server	Yes	no	no
Trauma Module	Yes	No	No
Osteotomy Module	Yes	Yes	Yes
Generic Measurements	Yes	Yes	Yes
Spine measurements	Yes	Yes	Yes
Lower Limbs measurements	Yes	No	Yes
Pre-operative planning	Yes	Yes	Yes
Templating (custom implant)	Yes	Yes	Yes
Templating (vendor specific implant)	Yes	No	Yes
Database	Yes	Yes	Yes
Online synchronization of database	Yes	No	Yes
Case Sharing	Yes	No	Yes
Control of life-saving devices	None	None	None
Human Intervention for interpretation and manipulation of images	Required	Required	Required
Ability to add additional Modules when available	Yes	Yes	Yes
Web Content	Yes	Yes	Yes

807.92(b)

Performance data for Surgimap 2.0 consisted in verification and validation activities. The following guidelines and standards were used throughout the software development process:

EN ISO 14971:2012	Medical Devices - Application of risk management to medical devices
IEC 62304:2006	Medical device software - Software life cycle processes
ANSI/IEEE Standard 829-2008	IEEE Standard for Software and System Test Documentation
FDA Guidance	Guidance for Industry and FDA Staff - Guidance for the content of premarket submissions for software contained in medical devices (May 11, 2005)

Software verification and validation testing were conducted and documentation was 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." The software for this device was considered to be at a "Moderate" level of concern, since a latent design flaw might lead the user to inadequately plan a surgery and thus indirectly injure patients.