DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 27, 2017

Scopis GmbH
Christopher Özbek, CTO
Heinrich-Heine-Platz 10
Berlin, Germany D-10719

Re: K171661
Trade/Device Name: Scopis Extended Instrument Set EM
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: August 24, 2017
Received: August 28, 2017

Dear Christopher Özbek:

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 (DICE) 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 (DICE) 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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*

K161491

Device Name
Scopis Hybrid Navigation System EM

Indications for Use *(Describe)*

The Scopis Hybrid Navigation System EM is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to the following ENT procedures:
• Transsphenoidal access procedures;
• Intranasal procedures;
• Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies;
• ENT related anterior skull base 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.

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SECTION 5 510(k) Summary

510(k) Summary

Scopis Extended Instrument Set EM

1. Submitter Information

Submitter: Scopis GmbH

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Contact: Dr. Christopher Özbek
Chief Technical Officer

Date Prepared: May 31, 2017

2. Device Information

Trade Name: Scopis Extended Instrument Set EM

Common Name: Image Guided Surgery System

Classification: Class II per 21 CFR 882.4560

Classification Name: Ear, Nose, and Throat Stereotaxic Instrument

Product Code: PGW

3. Purpose of Submission

The purpose of this submission is to gain clearance for an extension to the previously cleared Image Guided Surgery System.

4. Predicate Device Information

The *Scopis Extended Instrument Set EM* described in this submission is substantially equivalent to the following predicates:

Predicate Device	**Manufacturer**	**510(k) No.:**
Fiagon Navigation – Extended Instrument Set ENT	Fiagon GmbH	K141456
Cranial Image Guided Surgery System.	BrainLAB AG	K092467

5. Device Description

The Scopis Extended Instrument Set EM is a set of accessories for the Scopis Hybrid Navigation Unit EM and is intended to localize the patient, track the position of the patient, display the position of navigated instruments on a model of the patient's anatomy based on preoperative images (CT or MRI) using electromagnetic tracking technology. The position of the instruments and the patient are localized within an electromagnetic field produced by a field generator. The navigation of instruments relative to the patient's anatomy is established via registration of the patient's anatomy to the image set via fiducial markers, anatomical landmarks, or surface matching. The position of navigated instruments is then displayed on the model from the image set.

The Scopis Extended Instrument Set EM consists of:

1. Navigation Software (NOVA AR)
2. Navigated instruments with integrated localizers
3. Patient tracker with integrated localizer
4. Non-tracked accessories for mechanical fixation

6. Intended Use

The Scopis Extended Instrument Set EM is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to the following ENT procedures:

- Transsphenoidal access procedures;
- Intranasal procedures;
- Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies;
- ENT related anterior skull base procedures.

7. Comparison of Technological Characteristics

The substantial equivalence of the Scopis Extended Instrument Set EM to the predicates is shown by similarity in intended use, indications for use, materials, and performance. Both the Scopis Extended Instrument Set EM and the predicates utilize:

- Electromagnetic tracking technology for navigation.
- Fiducial or anatomical reference points for procedure registration to the image-based model of the patient's anatomy.
- Tracking of the navigation instruments via localizers mounted in the tip of the instruments.
- Use of CT or MR image sets as reference images for the image-based model of the patient's anatomy.

- Software functionality for pre-operative planning for points, lines and shapes.
- Image injection into intra-operative imaging modalities

All devices are subject to the same cyber security threat model of a networked PC with software and patient image data in a protected hospital environment.

8. Performance Data

Bench testing of the navigation accuracy was performed to establish the substantial equivalence to the respective predicate devices:

The measured navigation accuracy of the corresponding Scopis Hybrid Navigation System EM (cf. 510(k) No. K161491) is 0.49 ± 0.27 mm for the Precision Pointer EM compared to the reported device navigation accuracy of 0.9 mm ±0.34 mm of the Fiagon predicate K133573.

The accessory set in this 510(k) reaches a bench accuracy of 0.64 ± 0.27 mm with the use of the Registration pointer EM-D compared to the Fiagon predicate device K141456 with a bench accuracy 0.7 mm to 1.2 mm ± 0.29 mm to 0.42 mm.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the Scopis Extended Instrument Set EM has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.