July 23, 2018

Voyager Therapeutics, Inc.
Lynn Bayless
Director, Regulatory Affairs
75 Sidney Street
Cambridge, Massachusetts 02139

Re: K180854
Trade/Device Name: Voyager Trajectory Array Guide (V-TAG)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: June 20, 2018
Received: June 21, 2018

Dear Lynn Bayless:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Valerie A. Flournoy -S

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180854

Device Name
Voyager Trajectory Array Guide (V-TAG)

Indications for Use *(Describe)*
The V-TAG is intended to assist with stereotactic guidance, placement, and fixation for the operation of surgical instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and perioperative MR imaging. These procedures include laser coagulation, biopsies, catheter placement and electrode placement 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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3 510(K) SUMMARY

SUBMITTER:	Voyager Therapeutics, Inc 75 Sidney Street Cambridge, MA 02139 USA (857) 259-5340
CONTACT PERSON:	Lynn E. Bayless, MS, RAC
DATE PREPARED:	June 12, 2018
DEVICE TRADE NAME:	V-TAG™
COMMON NAME:	Stereotaxic instrument
CLASSIFICATION NAME:	Stereotaxic instrument
CFR CITATION:	882.4560
PRODUCT CODE:	HAW
PREDICATE DEVICE:	Monteris UFO (K090240)

3.1 Device Description

The V-TAG™ device is a single-use, skull-mounted, rigid trajectory array guide used in stereotactic surgical procedures in adults. The V-TAG can be manipulated to provide a wide range of surgical trajectories into the head. An image-guided neuronavigational system loaded with a stereotactic surgical plan is used to align the V-TAG to the planned trajectory; once aligned, the V-TAG is securely locked to provide a stable instrument guide. After positioning of the V-TAG, magnetic resonance imaging (MRI) is used to confirm alignment with the planned trajectory. Intracranial placement of a neurosurgical device or surgical instrument using the V-TAG device is only to be performed after MRI confirmation of the trajectory.

3.2 Indication for Use

The V-TAG is intended to assist with stereotactic guidance, placement, and fixation for the operation of surgical instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and perioperative MR imaging. These procedures include laser coagulation, biopsies, catheter placement and electrode placement procedures.

3.3 Technological Characteristics

The V-TAG device is a single use, MR compatible, sterile medical device consisting of a Base that is temporarily attached to the skull with four bone screws during the surgical procedure , a trajectory Guide containing seven channels to guide the insertion of 14-gauge neurosurgical devices or instruments, a Handle to assist with alignment using standard stereotactic surgical procedures, a Center Adaptor to identify the center trajectory of the Guide, an Imaging Cartridge to be filled with an FDA approved diluted gadolinium-based contrast agent (not included, no patient contact), and a Reducer for use with 16-gauge neurosurgical devices or instruments. **Table 1** demonstrates substantial equivalence of the V-TAG to the predicate device.

Table 4: Substantial Equivalence: V-TAG to the Predicate Device (Monteris Medical-UFO™)

Parameter	Predicate Device: Monteris Medical UFO™	510(k) Device: V-TAG™
K Number	K090240	-
Product	Monteris Medical UFO	Voyager Trajectory Array Guide
Manufacturer	Monteris Medical, Inc.	Voyager Therapeutics, Inc.
Indication for use	The Monteris Medical UFO is intended to provide stereotactic guidance, placement and fixation for the operation of instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and (or) perioperative MR or CT imaging. These procedures include laser coagulation, biopsies, catheter placement and electrode procedures.	The V-TAG is intended to assist with stereotactic guidance, placement, and fixation for the operation of surgical instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and perioperative MR imaging. These procedures include laser coagulation, biopsies, catheter placement, and electrode placement procedures.
Principal Operator	Neurosurgeon	Neurosurgeon
Use Location	MRI Suite and OR	MRI Suite and OR
Operating Principle	Stereotactic guiding & fixation device	Stereotactic guiding & fixation device
Design Principle	Ball and socket joint on a 3-leg support using 3 bone screws and 9 spikes	Ball and socket joint fixed to skull using 4 bone screws

Parameter	Predicate Device: Monteris Medical UFO™	510(k) Device: V-TAG™
"Frameless" stereotaxy	Yes	Yes
MRI Compatible	Yes	Yes
Single use disposable	Yes	Yes
Facilitates selection of trajectory	Yes	Yes
Provides alignment for neurosurgical device insertion	Yes	Yes
Facilitates temporary fixation of neurosurgical device	Yes	Yes
Verification of trajectory alignment by MRI	Yes	Yes
Range of motion	15 degrees angular (pre-drilled holes) or 58 degrees angular (no pre-drilled entry hole), 360 degrees rotation	45 degrees angular, 360 degrees rotation
Burr hole size	< 14 mm	< 14 mm
Bilateral option	Yes	Yes
Multi-lumen spacing	Single lumen	7 lumens, 2.5 mm spacing
Sterilization Method	Ethylene oxide	^{60}Co Gamma Irradiation

3.4 Non-Clinical Test Results

The non-clinical tests performed were prospectively identified to show substantial equivalence to the predicate device.

All testing was conducted on the subject device.

All biocompatibility testing was in compliance with the FDA GLP regulations (21 CFR 58).

The device passed all tests that were conducted indicating substantial equivlence.

Thus, the non-clinical performance data demonstrate that the V-TAG performs as indicated in the **Instructions for Use**, and is substantially equivalent and performs as well as the predicate device that is marketed for the same intended use.

The tests conducted, method and overall conclusion is provided in **Table 2**.

Table 5: Summary Nonclinical Test Results

Test	Test Method	Conclusion
Biocompatibility:		
Cytotoxicity: 1X MEM Elution (Product and packaging performed according to USP)	ISO 10993-5-Part 5: Tests for In Vitro Cytotoxicity In vitro mammalian cell culture test	Non-cytotoxic. No evidence of cell lysis or toxicity. Grade <2 (mild reactivity)
Intracutaneous Toxicity	UNI EN ISO 10993-10-Part 10: Tests for Irritation and Skin Sensitization 0.9 % Sodium Chloride Solution: Sesame Oil, NF Intracutaneous injection in rabbits.	No biological response elicited. No adverse observations noted throughout the duration of the test. Overall mean score was 0.0 for both the sodium chloride and sesame oil test article extracts.
Systemic Toxicity: ISO Acute Systemic Injection Test	UNI EN ISO 10993-11-Part 11: Tests for Systemic Toxicity 0.9 % Sodium Chloride Solution: Sesame Oil, NF	Study requirements met. No biological response elicited. No mortality nor evidence of systemic toxicity.
Sensitization	UNI EN ISO 10993-10- Part 10: Tests for Irritation and Skin Sensitization ASTM F 720-81 (2002) 0.9% Sodium Chloride Solution: Sesame Oil, NF	Non-sensitizing. Test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
Material Mediated Pyrogenicity	US, General Chapter <151>, Pyrogen Test 0.9% Sodium Chloride Solution	Test article deemed non-pyrogenic. No animal experienced a temperature rise 0.5°C or more above its baseline.

Test	Test Method	Conclusion
Bench Performance Testing:		
MRI Compatibility	ASTM 2503-13 ASTM F2052-14 ASTM F2213-06 Testing was not performed on Center Adaptor or Handle as they are not intended for use in a MR environment.	V-TAG Base, Guide, Imaging Cartridge, and Reducer are MR safe.
Integrity Testing- Zero time and 1 year accelerated:		
Integrity Testing- Zero Time and 1 year accelerated	Evaluated dimensional verification, device stability, seal integrity of the Image Cartridge, and bond and joint strength for the Image Cartridge, Reducer Handle and tip.	Predetermined test specifications were met for all tests at both time points.