June 30, 2020

Innovasis, Inc.
Marshall Mccarty
Director QA/RA
614 East 3900 South
Salt Lake City, Utah 84107

Re: K200874
Trade/Device Name: TruView Light Cable, TruView Lateral Retractor Light Cable, Bifurcated Light Cable With Universal End
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: Class II
Product Code: FST
Dated: March 31, 2020
Received: April 1, 2020

Dear Marshall Mccarty:

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,

Colin Kejing Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
TruView™ Light Cable

Indications for Use *(Describe)*
The TruView Light Cable is intended to provide surgical site illumination from a fiber optic light source.

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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"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."

5.0 510(k) Summary Report:

TruView™ Lateral Retractor Light Cable

Company: Innovasis, Inc.
614 E. 3900 South
Salt Lake City, UT 84107

Contact: Marshall C. McCarty
Phone: (801) 261-2236 x8012
mmccarty@innovasis.com

Trade Name: TruView Light Cable

Common Name: Fiber Optic Light Cable

Classification: Regulation No.: 21 CFR 878.4580
Class 2
Product Code: FST
Review Panel: General & Plastic Surgery

Primary Predicate: K042034 NuVasive, Inc. *MaXcess Light Guide*
This predicate has not been subject to a design-related recall.

Additional Predicate:
K901035 Cuda Products Co./Sunoptic Technologies
Fiberoptic Light Cable

Device Description: The TruView Light Cable is a fiber optic surgical light designed to be compatible with a variety of fiber optic light sources.

Performance Data: (Non-clinical)—The TruView Light Cable was subjected to three (3) performance tests that indicated it performs in accordance with its intended use. Testing included a Fit Test to show that it is compatible with the retractor; a Collateral Heating Test to show that the cable, when used with the identified light source, does not pose a risk to the surgeon or operating room users (burn/injury to user); and an Intensity Test to show that the cable, when used with the identified light source and the worst-case retractor blade configuration, does not pose a risk to the patient (burn/patient injury).

The subject TruView Light Cable met the acceptance criteria for the testing performed.

Materials: The TruView Light Guide contains borosilicate glass optical fibers wrapped in a silicone sheath and has surgical stainless-steel couplings per ASTM F899.

The TruView sterilization trays are comprised of Anodized 5052 Aluminum and have components made of Nylon, Stainless Steel, Polypropylene, and RADEL per ASTM D6394 SP031.

Indications for Use: The *TruView Light Cable* is intended to provide surgical site illumination from a fiber optic light source.

Comparison of Technological Characteristics with the Predicate Devices:

The *TruView Light Cable* has been subjected to risk analysis, engineering analysis and testing to recognized standards and has been shown to be substantially equivalent to the predicate devices, NuVasive *MaXcess Light Guide* (K042034) and Sunoptic *Fiberoptic Light Cable* (K901035).

- Technology is substantially equivalent.
- Design is substantially equivalent.
- Size is substantially equivalent.
- Indications for use (intended use) are substantially equivalent.
- Materials (biocompatibility profile) are substantially equivalent.

Conclusion: The overall technology characteristics and mechanical performance data lead to the conclusion that the subject device is substantially equivalent to legally marketed predicate devices.