July 22, 2022

NeuraMedica, Inc.
Rachel Dreilinger
CEO
402 Beavercreek Road, Suite 110
Oregon City, Oregon 97045

Re: K213813
Trade/Device Name: DuraFuse Clip and Applier System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: June 17, 2022
Received: June 21, 2022

Dear Rachel Dreilinger:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K213813

Device Name
DuraFuse Clip and Applier System

Indications for Use *(Describe)*

DuraFuse Clips are indicated for open and tubular retractor procedures of the spine in the prone position for approximation/attachment and/or closure of the dura mater in neurosurgical and orthopedic spine 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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510(k) Summary

Submitter's Information

NeuraMedica Inc.
1515 7th STE A
Oregon City, OR 97045
503-914-0723

Contact Person: Rachel Dreilinger, CEO
rachel@neuramedica.com

Date Prepared: June 17, 2022

Device Information

Device:	Trade Name:	DuraFuse Clip and Applier System
	Classification Name:	Clip, Implantable
	Regulation Number:	878.4300
	Product Code:	FZP
	Classification Panel:	General & Plastic Surgery
	Classification:	Class 2 Device

Predicate Device

The predicate device with which NeuraMedica DuraFuse Clips claims substantially equivalency is below:

Company:	United States Surgical Corporation
Device:	Auto Suture Modified VCS Clip Applier
510(k):	K962043, Cleared September 23, 1996

Device Description

NeuraMedica's DuraFuse Clip is a small, bioabsorbable, non-penetrating clip for rapid closure of the dura mater during spine surgery. DuraFuse Clips are applied individually using the reusable stainless steel NeuraMedica Applier. The applier has a low profile that allows visibility for implantation of clips in open or tubular retractor procedures.

NeuraMedica DuraFuse Clips are provided sterile and labeled for single use. Dural Clips are sterilized via a validated e-beam dose.

NeuraMedica's DuraFuse Applier is autoclavable. It is provided non-sterile.

Indication for Use

DuraFuse Clips are indicated for open and tubular retractor procedures of the spine in the prone position for approximation/attachment and/or closure of the dura mater in neurosurgical and orthopedic spine procedures.

Comparison of Indications for Use

The predicate device is indicated for use in vascular anastomosis as well as approximation of dural tissue. DuraFuse Clips have limited indications for use to approximation of dural tissue.

The predicate device does not specify the type of procedure, open or minimally-invasive, while the indication for DuraFuse Clips specifies the types of procedures that were tested during development, open and tubular-retractor.

The differences in Indications for Use Statements do not alter the therapeutic use of the device in spine surgery to approximate dura tissue nor do they raise new questions of safety or effectiveness.

Comparison of Technological Characteristics:

The predicate and DuraFuse Clips function the same, they apply pressure to the everted edges of the dura to seal the spinal column and allow the dura to heal. At a high level, the subject and predicate devices are based on the following same technological elements:

- Similar shape and size
- Clips with rounded tips to avoid tissue penetration and reduce the potential for CSF leakage
- Hold everted edges of dura together to allow healing

The following technological differences exist between the subject and predicate device:

- Predicate clips are metal while the subject device is a bioabsorbable material
- Predicate clips are provided pre-loaded in an applier, while the subject device is supplied separately from a reusable applier
- Predicate device has an accessory tool for removal or repositioning of clips, while the subject device has a reusable applier that can be used for removing or repositioning clips

Performance Data - Biocompatibility

Biocompatibility evaluation was performed on the DuraFuse Clips consistent with ISO 10993-1. Testing demonstrated passing results for cytotoxicity, irritation, and sensitization. Implantation testing demonstrated that long-term tissue responses are not expected to occur from the use of DuraFuse Clips.

Performance Data – Non-Clinical

Bench top testing using a synthetic dural model was performed and demonstrated that the DuraFuse Clips can successfully approximate synthetic dural material in defects from 1 cm to 10 cm without fluid leakage or damage to dura. The bench top data support the equivalent performance to the predicate device at higher pressures than could be evaluated in the in vivo animal model.

Human Factors testing in a human cadaver model was completed in open and tubular retractor procedures. Fourteen experienced surgeons evaluated the DuraFuse Clip and Applier and found that:

- All components are easy to use
- Applier can be used with one hand
- Applier allows visibility of the surgical site in open and tubular retractor procedures
- Packaging allows the user to easily remove clips for implantation
- Clips can be applied successfully based on the information in the Instructions For Use

Performance Data – Animal Study

NeuraMedica has demonstrated equivalence of the proposed device to the predicate device in a swine model.

Eight swine underwent creation of an approximately 1 cm durotomy overlying the L2/3 intervertebral discs and was then treated with the test or control article. Animal health was monitored, including incision site and clinical observations, neurological exams, body weight/condition, and clinical pathology, at pre-determined, regular intervals. CT scans of the head/brain and lumbar spine were performed before and before necropsy. Blood samples for clinical pathology were collected prior to surgery and prior to necropsy. On Day 14 or 90, a CSF sample was collected, a CT myelogram was performed, the animals were euthanized, and a comprehensive necropsy followed by histomorphological examination was performed. Assessment of dural contiguity at

treatment sites was performed, specifically including indication of any presence of meningocoele/pseudomeningocoele.

After 14 or 90 days in the porcine spinal laminectomy and durotomy model, the DuraFuse Clip was associated with favorable tissue responses and dural closure with no evidence of CSF leakage. All parameters evaluated were comparable between the test and control groups.

Conclusion

In summary, NeuraMedica's DuraFuse Clip and Applier System has the same intended use as the predicate device, are similar in size, and are used in a cleared anatomical location, spine, as the currently cleared device The Dural Clips are sterile and non-pyrogenic. Biocompatibility testing, bench testing and comparative animal testing demonstrate the equivalence of the NeuraMedica DuraFuse Clip and Applier System to the predicate device and that the technological differences do not raise any new concerns of safety and effectiveness.

Based on the 510(k) summaries and the information provided, we conclude that NeuraMedica DuraFuse Dural Clip and Applier System is substantially equivalent to the predicate device, Auto Suture Modified VCS Clip Applier (K962043).