September 29, 2025

Tulavi Therapeutics, Inc.
% Janice Hogan
Regulatory Counsel
Hogan Lovells
555 13th St N.W.
Washington, District of Columbia 20004

Re: K252051
Trade/Device Name: allay™ Nerve Cap (TL5515-1); allay™ Nerve Cap (TL5515-2); Delivery Tips (TL-7627)
Regulation Number: 21 CFR 882.5260
Regulation Name: In situ polymerizing peripheral nerve cap
Regulatory Class: Class II
Product Code: SBG
Dated: July 31, 2025
Received: July 31, 2025

Dear Janice Hogan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Digitally signed by Adam D. Pierce -S
Date: 2025.09.29 16:42:47 -04'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252051

Please provide the device trade name(s).

allay™ Nerve Cap,
Delivery Tips

Please provide your Indications for Use below.

The allay™ Nerve Cap is indicated for use in individuals weighing 25 kg or more as a physical barrier to separate the peripheral nerve end from the surrounding environment to reduce the risk of the development of a symptomatic neuroma.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

Applicant Name:	Tulavi Therapeutics, Inc. (“Tulavi”)
Applicant Contact:	Joshua Vose, MD, MBA
Applicant Address:	160 Knowles Drive Los Gatos, CA 95032
Applicant Telephone:	706.951.0798
Applicant Email:	josh@tulavi.com
Prepared On:	September 25, 2025

Correspondent Name:	Hogan Lovells
Correspondent Contact:	Mrs. Janice Hogan, JD
Correspondent Address:	555 13th St N.W. Washington, DC 20004
Correspondent Telephone:	267.675.4611
Correspondent Email:	Janice.hogan@hoganlovells.com

Device Trade Name:	allay™ Nerve Cap
Common Name:	Nerve Cap
Classification Name:	In situ polymerizing nerve cap
Regulation #:	21 CFR §880.5260
Product Code(s):	SBG

Predicate Name:	allay™ Nerve Cap
Predicate Number:	DEN230061
Predicate Product Code:	SBG

1. Device Description

The allay™ Nerve Cap is a sterile, absorbable, in situ forming, hydrogel barrier composed of water and polyethylene glycol (PEG) that reduces the risk of neuroma formation by providing a protective cover around the end of a nerve. The hydrogel forms in seconds after delivery of the precursor solutions around a nerve placed in a temporary silicone Cap Form. The Cap Form is then readily removed and discarded, leaving the nerve end wrapped in a transparent compliant gel that conforms to the nerve to prevent nerve outgrowth from the proximal stump for over 3 months, the critical period during which neuroma formation can occur. The hydrogel Nerve Cap is biocompatible, non-constrictive and non-neurotoxic and is absorbed from the site within 8 months with no evidence of systemic toxicity.

The device consists of various components for the preparation of the hydrogel, a dedicated applicator for the mixing and delivery of the two-component PEG/Accelerator Solutions, and temporary silicone Cap Forms. The allay™ Nerve Cap system is provided in a plastic tray sealed in a sterile, peelable outer pouch. The product is available in two sizes of a Small Nerve Set, for nerves less than 4 mm in diameter, and a Large Nerve Set, for nerves greater than 4 mm in diameter and less than 7 mm in diameter. The allay™ Nerve Cap system includes a Powder Vial/Vial Adapter, Diluent Solution, Acceleration Solution, Dual Applicator and Adapter, Delivery Tip with Blunt Needle, and the Cap Forms [Small Nerve Set (l, 2, 3, and 4 mm) and Large Nerve Set (5, 6, and 7 mm)]. As a convenience for users, Delivery Tips are also provided separately if needed. They are provided in boxes that consist of six independently packaged, sterile Delivery Tips. They are identical to the Delivery Tips provided in the complete allay™ Nerve Cap kit, including with respect to dimensions, materials, use, and manufacturing.

The allay™ Nerve Cap is a single use device that is provided sterile and is strictly for prescription (Rx) use only.

2. Indications for Use

The indications for use for the allay™ Nerve Cap are as follows:

> *The allay™ Nerve Cap is indicated for use in individuals weighing 25 kg or more as a physical barrier to separate the peripheral nerve end from the surrounding environment to reduce the risk of the development of a symptomatic neuroma.*

This 510(k) expands the patient population in the indications for use statement for the previously granted a De Novo (DEN230061) for the allay™ Nerve Cap. The device is only available with prescription (Rx). Federal law restricts this device to sale by or on the order of a physician.

3. Summary Technological Characteristics

This 510(k) includes the same allay™ Nerve Cap device, which was granted a De Novo (DEN230061) on July 16, 2024, with no changes to the design, materials, use, or methods of manufacture. The only changes

included in this 510(k) include the expansion of the patient population in the Indications for Use and minor revisions to the device packaging. These changes are supported by packaging testing, a biocompatibility assessment per ISO 10993-1, and labeling changes limiting the use in patients weighing at least 25 kilograms and a maximum use of one allay™ Nerve Cap kit for patients between 25 - 58kg.

4. Performance Data

4.1. Biocompatibility

The final finished allay™ Nerve Cap was assessed in accordance with ISO 10993-1:2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," and the FDA guidance, "Use of International Standard ISO-10993, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process." The allay™ Nerve Cap was determined to be biocompatible: non-cytotoxic, non-sensitizing, non-toxic, non-irritant, non-hemolytic, non-pyrogenic, non-hemotoxic, and non-genotoxic for the intended use population.

4.2. Packaging and Shelf Life

Packaging Performance Qualification was completed to demonstrate that the sterile, finished Delivery Tip package met all the specifications for product performance. Testing was completed in accordance with ASTM D4169-22, ASTM D4332-22, ASTM F2096-11, and ASTM F88/F88M-21.

4.3. Prior Testing

Tulavi has relied on the benchtop testing, human factors validation, non-clinical (animal) testing, sterilization validation, shelf-life and packaging validation testing completed for the allay™ Nerve Cap (DEN230061), since there have been no changes to the device design, materials or methods of manufacture.

All previously performed testing confirms that the device performs as intended and meets predefined acceptance criteria that conform to the established design specifications, including after formation close to the device performance threshold and over the product lifecycle. These performance data support the overall safety, performance and deliverability of the allay™ Nerve Cap, complementing the chemical characterization, biocompatibility, and *in vivo* preclinical testing.

5. Substantial Equivalence

The allay™ Nerve Cap has the same intended use, principles of operation, technological characteristics, and similar indications as the predicate allay™ Nerve Cap. The minor differences in the indications and packaging do not raise any new questions of safety or effectiveness. Performance data demonstrates that the allay™ Nerve Cap is as safe and effective as the predicate. Thus, the allay™ Nerve Cap is substantially equivalent to the predicate device.

6. Conclusion

The allay™ Nerve Cap, including the additional patient population of patients weighing 25kg and above (subject device) is substantially equivalent to the predicate device (allay™ Nerve Cap, DEN230061).