inomed Medizintechnik GmbH
Shuofei Cheng
Regulatory Affairs Manager
Im Hausgruen 29
Emmendingen, Baden-Wuerttemberg 79312
Germany

November 11, 2022

Re: K212164
Trade/Device Name: Mapping Suction Probe
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: September 29, 2022
Received: October 3, 2022

Dear Ms. Cheng:

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,

Patrick Antkowiak -S

for
Jay Gupta
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)*
K212164

Device Name
Mapping Suction Probe 3/90 monopolar (Art. No. 525650), Mapping Suction Probe 3/130 monopolar (Art. No. 525651), Mapping Suction Probe 2/90 monopolar (Art. No. 525655), Mapping Suction Probe 2/130 monopolar (Art. No. 525656)

Indications for Use *(Describe)*
The Mapping Suction Probe is a surgical instrument that allows the surgeon to remove secretions and test surgical tissue with nerve stimulation simultaneously and with the same instrument. The instrument is intended for use only by a licensed physician and in conjunction with compatible nerve locator monitor systems.

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

Submission Date:	08 July 2021
510(k) Holder:	inomed Medizintechnik GmbH Im Hausgrün 29 79312 Emmendingen, Germany
Contact Person:	Shuofei Cheng Ph.D. Phone: +49 7641 9414 849 Email: S.Cheng@inomed.com
Manufacturing Site:	inomed Medizintechnik GmbH Im Hausgrün 29 79312 Emmendingen, Germany
Name of Device:	Mapping Suction Probe
Common and Classification Name:	Suction Stimulator Probe
Classification Name:	Surgical nerve stimulator/locator (21 CFR 874.1820)
Regulatory Class:	II
Product Code:	ETN
Regulation Medical Specialty:	Surgical nerve stimulator/locator

	Predicate 510(k) Number	Predicate Manufacturer/ Model
Predicate Device:	K110712	Neurovision™ Medical Products, Inc.™./ DryTouch Suction Stimulator Probe

Device Description:	The Mapping Suction Probe is a surgical instrument which combines a surgical suction instrument and a monopolar stimulation probe in one instrument.

The stimulation function of the Mapping Suction Probe is used for monopolar stimulation during intraoperative surgical interventions and is connected to electrical stimulators of neuromonitoring devices outside the sterile field via an appropriate integrated connection cable. To ensure a correct monopolar stimulation, a counter electrode is also included in the sterile package which must be placed at the resection margin.

The suction function of the Mapping Suction Probe is used for aspiration during tumor resection and is connected to suction devices via a tube, which is not part of the delivered package.

Indications for Use:

The Mapping Suction Probe is a surgical instrument that allows the surgeon to remove secretions and test surgical tissue with nerve stimulation simultaneously and with the same instrument.

The instrument is intended for use only by a licensed physician and in conjunction with compatible nerve locator monitor systems.

Comparison of Technological Characteristics with the Predicate Device:

Characteristic	Subject device	Predicate device
System	Mapping Suction Probe	DryTouch Suction Stimulator Probe
Manufacturer	inomed Medizintechnik GmbH	Neurovision Medical Produtcts, Inc.
510(k)Number	K212164	K110712
Picture		
Indications for use	The Mapping Suction Probe is a surgical instrument that allows the surgeon to remove secretions and test surgical tissue with nerve stimulation simultaneously and with the same instrument. The instrument is intended for use only by a licensed physician and in conjunction with compatible nerve locator monitor systems."	The Suction Stimulator Probe is a dedicated manual surgical instrument that allows the surgeon to clear secretions and test surgical tissue with nerve stimulation at the same time and with the same instrument. It is intended for use only by a licensed physician and in conjunction with the Neurovision SE (Nerve; na) Nerve locator Monitor System.
Contraindications	The use of muscle relaxants is contraindicated, as these cause significant	The use of paralytic anaesthetics will cause abnormal EMG performance. Advise the

	reductions in the evoked muscle potentials.	anaesthesia provider of this contraindication.
User group	Surgeon and Neurophysiologist	Licensed physician
Risk management	Risk Management according to standard: ISO 14971: 2019	Risk Management according to standard: ISO 14971: 2007
Operating Principle	• The device is a disposable surgical instrument • The product combines a surgical suction instrument and a monopolar stimulation probe simultaneously • Monopolar stimulation on the non-insulated tip of the suction probe component to localize and identify nervous structures and to prevent their damage during surgery. • To ensure a specific stimulation at the point of interest, the residual metal part of the probe's shaft is insulated. • The connector on the end of the suction probe component is for mechanical connection to suction devices via suction tubes. • Depending on the case, the suction function is used for aspiration during tumor resection or to clear the surgical field from fluids for better visualization.	• The device is a disposable surgical instrument • The product combines a surgical suction instrument and a monopolar stimulation probe simultaneously • Monopolar stimulation on the non-insulated tip of the suction probe component to localize and identify nervous structures and to prevent their damage during surgery. • To ensure a specific stimulation at the point of interest the residual metal part of the probe's shaft is insulated. • The connector on the end of the suction probe component is for mechanical connection to suction devices via suction tubes. • Depending on the case the suction function is used for aspiration during tumor resection or to clear the surgical field from fluids for better visualization.
Materials	The instrument consists of a stainless-steel shaft, partially insulated with biocompatible PTFE and ending with an oblong hole suction.	The instrument consists of a stainless-steel shaft, partially insulated with biocompatible PTFE and ending with a ball- tip suction.
Tissue contact	The medical device comes in direct tissue contact.	The medical device comes in direct tissue contact.
Shelf life	3 years	1 year
Sterilization	• EO validation is compliant with ISO 11135:2014 + A1:2018 • residuals analysis is compliant with ISO 10993-7:2008 • The Sterility Assurance Level is 10^{-6} • Device is not labeled non-pyrogenic.	• EO validation is compliant with ISO 11135-1:2007 • EO residuals analysis is compliant with ISO 10993-7:2008 • The Sterility Assurance Level is 10^{-6} • Device is not labeled non-pyrogenic.
Product length	▪ 9 cm ▪ 13 cm	• 13 cm

Inner diameter (Lumen)	• 9fg • 6fg	• 6fg
Insulated tip length	2mm	2mm
Accessories	• 1 Subdermal Needle Electrode (black lead wire) 3.0m wire, 20 mm Needle-0.45mm gauge • Connection Cable (red) 3.0m cable length	• 2 Neurovision™ Subdermal Needle Electrodes (white and green lead wire) 2.5m wire,12 mm Needle-0.4 mm gauge, 27G • 2 Alcohol Wipes
Site of application	No specific site	No specific site
Duration of use	< 30 days	< 30 days
Single use or reusable	Single use	Single use
Provided sterile	Yes	Yes
Connector standard	DIN 42802	DIN 42802
Connector	Touch Proof	Touch Proof

Performance Data:

Biocompatibility: The Mapping Suction Probe and Needle Electrode component were tested according to the following standards:

- ISO 10993-1:2018
- ISO 10993-5:2009
- ISO 10993-7:2008
- ISO 10993-17:2002
- ISO 10993-18:2005

Test	Test Performed	Results and Conclusion
Cytotoxicity	Cell Growth Analysis via XTT-Staining	The results showed no reduction of cell proliferation and/or cell viability. With the highest extract concentration (100 %) the dehydrogenase activity was 101 %. Microscopically, no inhibition of cell growth and no cell lysis were observed at all extract concentrations used.

		Conclusion: The item under test is considered non-cytotoxic.
Sensitization	Guinea Pig Maximization Test with polar and non-polar extract	The sensitization rate after application of the test item extract was 0%. Conclusion: The item under test is considered to have no sensitizing properties.
Irritation / Intracutaneous Reactivity	Irritation Test (Intracutaneous Reactivity) in the Rabbit with polar and non-polar extract	The primary irritation index of the polar and the nonpolar test item extracts compared to the controls were 0. Conclusion: The item under test is classified as not irritant.
Acute Systemic Toxicity	Acute Systemic Toxicity in the Mouse with polar and non-polar extract	No compound-related mortalities and no other signs of toxicity were recorded within 72 hours post-dose for any of the animals. Conclusion: The item under test showed no acute systemic toxic characteristics.
Material Mediated Pyrogenicity	Rabbit Pyrogen Test according to USP	Temperature increase for each rabbit was not > 0.50°C. Conclusion: The materials of the item under test are considered non pyrogenic.
Hemolysis	Direct and indirect contact test under static conditions according to ASTM F 756-17	The data show that the haemolytic indices of the blood substrate supernatants with direct (0.11%) and indirect (0.08%) contact to the test item were below 2% and therefore the material is classified as non-haemolytic. Conclusion: The item under test does not induce haemolysis.
Bacterial Endotoxins	Limulus-Amoebocyte-Lysate (LAL) Test – Kinetic Turbidimetric Assay (KTA)	The endotoxin content of each test items was < 1.55 EU/test item. Conclusion: The test items are non-pyrogenic under consideration of the acceptance criterion (< 2.15 EU/device)

The tests are conducted on the Device: '525651 Mapping Suction Probe 3/130, monopolar'.

The following tests were performed for the Needle Electrode component.

Test	Test Performed	Results and Conclusion
Cytotoxicity	Cell Growth Analysis via XTT-Staining	The results showed no relevant reduction (- relevant meaning > 30 % reduction -) of cell proliferation and/or cell viability. With the highest extract concentration (100 %) the dehydrogenase activity was reduced to 89 %. Microscopically, slightly reduced cell growth was observable from 66.7 % extract concentration onwards. Slight cell lysis was observable only in the undiluted extract. Conclusion: The item under test is considered non-cytotoxic.
Sensitization	Guinea Pig Maximization Test with polar and non-polar extract	The sensitization rate after application of the test item extract was 0%. Conclusion: The item under test is considered to have no sensitizing properties.
Irritation / Intracutaneous Reactivity	Irritation Test (Intracutaneous Reactivity) in the Rabbit with polar and non-polar extract	The primary irritation index of the polar and the nonpolar test item extracts compared to the controls were 0. Conclusion: The item under test is classified as not irritant.

Acute Systemic Toxicity	Acute Systemic Toxicity in the Mouse with polar and non-polar extract	No compound-related mortalities and no other signs of toxicity were recorded within 72 hours post-dose for any of the animals. Conclusion: The item under test showed no acute systemic toxic characteristics.
Material Mediated Pyrogenicity	Rabbit Pyrogen Test according to USP	Temperature increase for each rabbit was not > 0.50°C. Conclusion: The materials of the item under test are considered non pyrogenic.
Bacterial Endotoxins	Limulus-Amoebocyte-Lysate (LAL) Test – Kinetic Turbidimetric Assay (KTA)	The endotoxin content of the test items was 0.6300, 0.7800 and 0.6600 EU/test item. Conclusion: The test items are non-pyrogenic under consideration of the acceptance criterion (< 20.0 EU/device)

Test results indicate that the Mapping Suction Probe and the Needle Electrode component comply with the applicable standards and demonstrated the safety of subject device.

Software: The Mapping Suction Probe does not contain any kind of software, and therefore, this section does not apply to it.

Electrical Safety: The Mapping Suction Probe is a device which is not electrically-powered, and therefore, this section does not apply to it.

Electromagnetic Compatibility: The Mapping Suction Probe is a device which is not electrically-powered, and therefore, this section does not apply to it.

Performance Testing – Bench: The Mapping Suction Probe was tested for performance in accordance with internal requirements and the following standards:

- IEC 60601-1:2005/AMD1:2012
- IEC 60601-1-2:2014
- IEC 60601-2-40:2016

- Electrical Tests: Electrical Conductivity, Dielectric Strength

  Functional Tests: Impedance Measurement, Stimulation

  Current Test Dimension Test: Dimension of Components
- Suction Performance Tests: Reached Vacuum in Air, Volumetric Flow Rate
- Mechanical Suction Tests: Deformation Test, Leakage Test
- Mechanical Tests: Pull-out Force Test, Distractive Force Test, Mechanical Stability Test, Bending Stress Test
- Insulation Test Shelf-Life Tests

The tests were conducted on the subject device Mapping Suction Probe and/or its component.

Performance Testing – Clinical	Clinical testing was not performed for the Mapping Suction Probe.
Conclusions	The testing and assessments performed demonstrate that the subject device performs comparable to the predicate device that is currently marketed for the same intended use.