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NEURENTMedical

TECHNICAL REPORT

Number:	(b)(4)
Revision:	
Title:	NEUROMARK™ System (b)(4)
Written By:	(b)(4)
Reviewed By:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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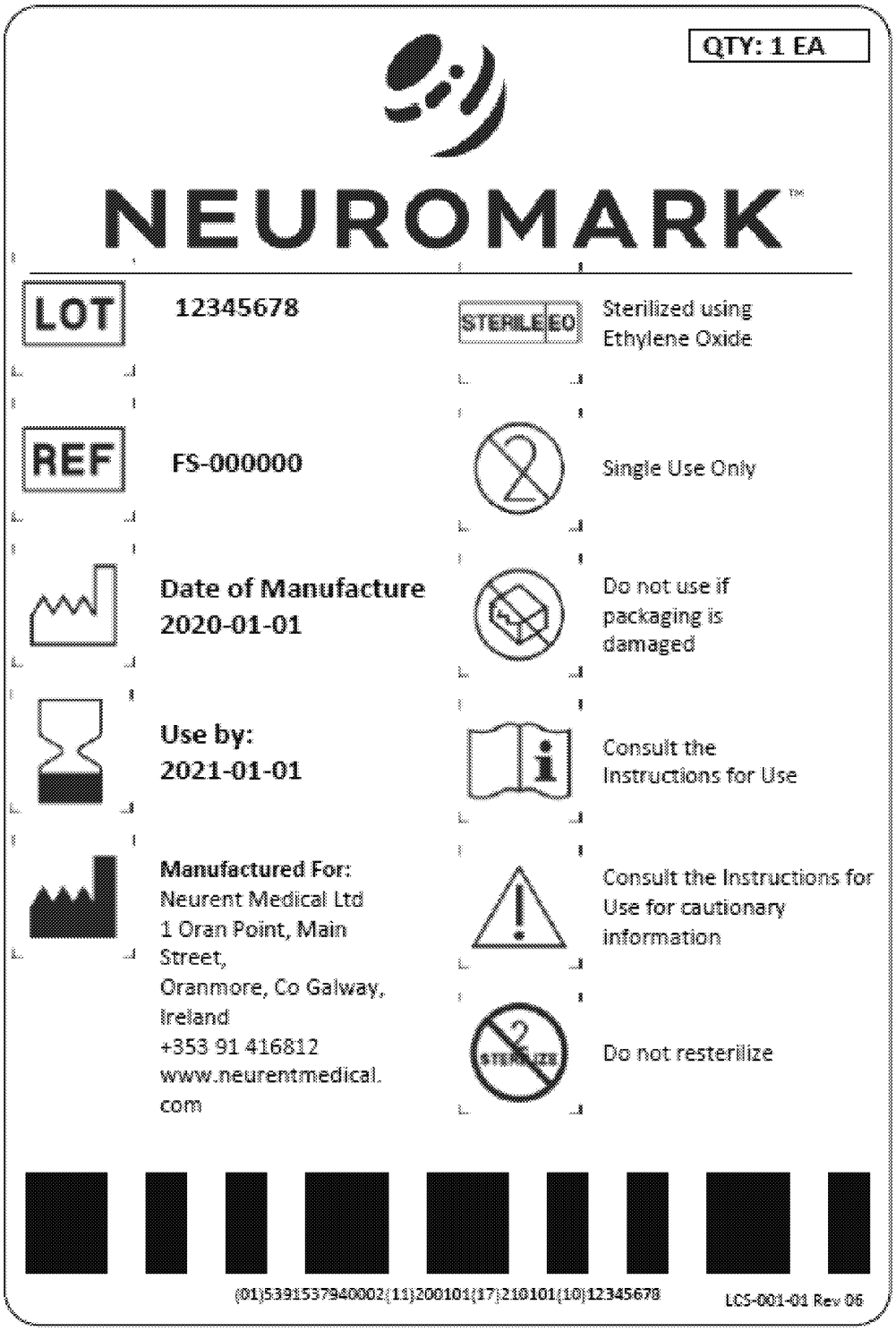
Attachment 08 – Predicate Device Current Packaging Label



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(b)(4), (b)(4) Testing Report

NEUROMARK™ System

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Document Author:

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Document Approvals:

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Response to FDA Interactive Questions of 5 Oct 2022

7 Oct 2022

Below are the FDA *interactive questions* followed by Neurent Medical's response.

Interactive Questions

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Hello Lindsay,

Thank you for sending the interactive questions. Attached is our response to the 3 questions. The following files are attached:

- Response to FDA Interactive Questions of 05Oct2022
- Attachment 1 Updated IFU redline
- Attachment 2 Updated IFU clean copy
- Attachment 3 Updated 510(k) Summary redline
- Attachment 4 Updated 510(k) Summary clean copy

Let me know if you need anything else.

Have a nice weekend,
Karen

From: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>
Sent: Wednesday, October 5, 2022 10:42 AM
To: Karen Peterson <karen@neurentmedical.com>
Cc: k222032@docs.fda.gov
Subject: K222032/S001: Interactive Questions

Hello Karen,

As you know, we are proceeding interactively with your submission for the Neuromark device modifications. I have three interactive questions for you (attached). If you could please provide responses to these questions by Monday, October 10, 2022 by COB that would be helpful. If you need more time, please let me know.

Thanks,
Lindsay

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Ph: 240-402-1462
Email: lindsay.devries@fda.hhs.gov

U.S. Food and Drug Administration

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Summary Report, NEUROMARK™ System

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15 Sept 2022: Below are the FDA *interactive questions* followed by Neurent Medical's response.

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October 26, 2022

Neurent Medical
Karen Peterson
Vice President Clinical, Regulatory & Quality
1 Oran Point, Main Street, Oranmore
Galway, Connaught H91D7X2
Ireland

Re: K222032
Trade/Device Name: NEUROMARK System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 28, 2022
Received: July 29, 2022

Dear Karen Peterson:

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

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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.

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Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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)*
K222032

Device Name
NEUROMARK® System

Indications for Use *(Describe)*
The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

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.

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510(K) SUMMARY

Date Prepared: Oct 20, 2022

Submitter Information:
Neurent Medical
1 Oran Point, Main Street
Oranmore, Co. Galway, H91 D7X2
Ireland

Establishment Registration: 3016813690

Contact Information:
Karen E. Peterson
Vice President Clinical, Regulatory & Quality
Neurent Medical
(651) 398-4341
karen@neurentmedical.com

Device Information:

Trade Name:	NEUROMARK® System [K222032]
Common Name:	Radiofrequency Probe
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	GEI
Classification:	Class II
Regulation Number:	21 CFR 878.4400
Predicate Device:	NEUROMARK® System [K212666]

Device Description:
The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis.

The NEUROMARK® System is composed of the NEUROMARK® Device and the NEUROMARK® Radiofrequency (RF) Console.

The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft, and treatment tip. The treatment tip, which is referred to as the End Effector, consists of an array of bipolar electrodes that deliver RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery. The shaft of the device is pre-shaped to aid access and delivery to the nasal cavity but is malleable to allow the user to bend or shape it to accommodate variations in anatomy to access the desired treatment area. The NEUROMARK® Device is operated via handle, slider and activation button. Once in the desired position within the nasal cavity, the operator moves the slider backwards which retracts the outer sheath, deploying the End Effector. Using the activation button, the user initiates a bio-impedance check to assess and confirm contact between the End Effector and the treatment area. Once the System confirms contact has been achieved, a subsequent press of the activation button initiates the RF energy delivery cycle. The NEUROMARK® Device is intended for single use and provided sterile (EO).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The NEUROMARK® Device is designed for use with the NEUROMARK® Radiofrequency (RF) Console; it includes features to allow compatibility and authentication once connected, via a flexible interface cable, to the Console.

The NEUROMARK® Console delivers, monitors and controls RF energy to the Device. The Console is mounted on an ergonomic mobile stand for ease of use. The Console includes a Graphical User Interface (GUI) which provides operational instructions for the procedure, directs the user to select nasal cavities for treatment, indicates when the device is in contact with tissue and ready to start treatment, provides status of therapy and indicates when the procedure is complete. The NEUROMARK® Console works in conjunction with software.

Indication for Use:
The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

Technological Characteristics:
The NEUROMARK® System (subject device) has the same indications for use and fundamental scientific technology as the predicate NEUROMARK® System [K212666].

The subject device has the same technological characteristics (i.e., principle of operation, basic design, functionality, energy type, biocompatibility, sterile packaging, shelf life, and sterilization) as the predicate device. The Treatment Tip (End Effector) of the subject device has different material and base component construction from that of the predicate device. The subject device has electrodes distributed over 4 proximal leaflets compared to 6 proximal leaflets in the predicate device. In addition, the subject device connector and interface cable was modified to simplify the connection of the device to interface cable.

Substantial Equivalence:
The NEUROMARK® System has the same indications for use and fundamental scientific technology as the predicate device. Evaluation of the impact of the device modifications was completed. No new risks were identified and relevant performance testing was repeated to ensure the subject device still meets intended use, product specifications, and performs similarly to the predicate device.

Performance Data:
Performance testing of the NEUROMARK® System consisted of design verification/validation testing, biocompatibility, software, and electrical and thermal safety testing to support the device modifications listed above. All testing passed and showed that the device meets design specifications and performed as intended.

Conclusion:
In conclusion, the indications for use and technological characteristics are the same as or equivalent to the predicate device. Performance testing has demonstrated that the subject device is as safe and effective and is substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Karen,

I have a requested modification to your 510(k) Summary (b)(4)

(b)(4)

Please send me a modified 510(k) Summary by COB tomorrow, Friday October 21, 2022. If there is a time issue, please let me know.

Thanks,
Lindsay

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Ph: 240-402-1462
Email: lindsay.devries@fda.hhs.gov

U.S. Food and Drug Administration

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NEURENTMedical

(b)(4)

(b)(4) Testing Report

NEUROMARK™ System

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Document ID:	(b)(4)
Revision:	

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October 26, 2022

Neurent Medical
Karen Peterson
Vice President Clinical, Regulatory & Quality
1 Oran Point, Main Street, Oranmore
Galway, Connaught H91D7X2
Ireland

Re: K222032
Trade/Device Name: NEUROMARK System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 28, 2022
Received: July 29, 2022

Dear Karen Peterson:

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division Dental and ENT Devices
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510(K) SUMMARY

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Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☐ **Traditional** ☐ **Abbreviated** ☒ **Special**

(Should be completed within 15 days of DCC receipt)
The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K222032 Date Received by DCC: July 12, 2022

Lead Reviewer: Lindsay DeVries, Au.D., Ph.D.

Center: CDRH Office: OHT 1 Division: DHT1B

Decision:

○ Accept. If Accept, notify submitter.

◉ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Special 510(k) Factors

(See "The Special 510(k) Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program).

Please complete the below questions to determine if the 510(k) is appropriate for review as a Special 510(k). Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the manufacturer legally authorized to market the predicate device.	☒	☐
Comments:		
2. Performance data are needed to evaluate the change. *If a manufacturer determines under their design control procedures that no additional verification or validation testing is necessary to evaluate a change, manufacturers may submit these changes as a Special 510(k) with a clear rationale supporting their conclusion that no performance data are necessary. When FDA does not agree with the manufacturer's assessment, FDA intends to continue with the additional Special 510(k) factors.*	☒	☐
Comments:		
3) There is a well-established method to evaluate the change. *Well-established methods include those used in the previously cleared 510(k), an FDA-recognized consensus standard or FDA guidance document, qualified medical device development tools (MDDTs), are widely available and accepted, or found acceptable through a different premarket submission by the same manufacturer of the predicate.*	☒	☐
Comments:		

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4) The data can be reviewed in a summary or risk analysis format. *The results from verification and validation associated with design or labeling changes should be able to be placed in a summary or risk analysis format without losing information necessary to support SE. Complete test reports should not be submitted in a Special 510(k). If complete test reports are submitted, FDA intends to assess whether the information can be reviewed in a summary format before converting to a Traditional 510(k).*	☐	☒
Comments:	(b)(4)	

Is the submission appropriate for review as a Special 510(k)? *Answer Yes if the change was submitted by the manufacturer of the predicate, well-established methods are available for any performance data necessary, and performance data can be reviewed in a summary or risk analysis format.*

- ○ Yes, submission is appropriate for a Special 510(k). Continue checklist below.
- ◉ No, submission is not appropriate for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional, and apply the Traditional checklist.

Concurrence for Converting a Special 510(k) to a Traditional or Abbreviated 510(k)

Records processed under FOIA Request 2024-2274, Released by CDRH on 09-09-2024

Note: Please send this to 510k Staff electronically.

Conversion Instructions

Digital Signature Concurrence Table	
Reviewer Sign-Off	Lindsay A. Devries -S 2022.07.18 14:06:51 -04'00'
Management Sign-Off (digital signature optional)*	Joyce C. Lin -S 2022.07.26 14:13:03 -04'00'

* Management review of checklist and concurrence with with decision required.

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NEURENTMedical

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Testing Report

NEUROMARK™ System

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Revision:	

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510(K) SUMMARY

(b)(4)

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(b)(4)

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Final (b)(4) Report

(b)(4)

TEST FACILITY

(b)(4)

SPONSOR

Neurent Medical
(b)(4)
No. 1 Oranpoint, Oranmore, Galway
H91 D7X2
Ireland

CONFIDENTIAL

STUDY TITLE

(b)(4)

TEST ARTICLE NAME AND IDENTIFICATION

(b)(4) NEUROMARK,
reference: (b)(4) NEUROMARK,
batch: (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

(b)(4) Protocol

TEST FACILITY

(b)(4)

SPONSOR

Neurent Medical
(b)(4)
No. 1 Oranpoint, Oranmore, Galway
H91 D7X2
Ireland

CONFIDENTIAL

STUDY TITLE

(b)(4)

TEST ARTICLE NAME AND IDENTIFICATION

(b)(4) NEUROMARK,
reference (b)(4) NEUROMARK,
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Appendix C. Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the application.

510(k)#: **Date Received by DCC:**

510(k) Lead Reviewer:

Center: **Office:** **Division:**

Decision: **Accept_____ Refuse to Accept_____**

If Accept, notify the submitter.

If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: Yes No

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Special 510(k) Factors (See "The Special 510(k) Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program) Please complete the below questions to determine if the 510(k) is appropriate for review as a Special 510(k). Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.			
		Yes	**No**
1.	**510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the manufacturer legally authorized to market the predicate device.**	☑	☐
	Comments: The 50(k) is submitted to modify a legally marketed device (predicate) and is submitted by Neurent Medical who are the manufacturer legally authorized to market the predicate device (K212666).		
2.	**Performance data are needed to evaluate the change.** *If a manufacturer determines under their design control procedures that no additional verification or validation testing is necessary to evaluate a change, manufacturers may submit these changes as a Special 510(k) with a clear rationale supporting their conclusion that no performance data are necessary. When FDA does not agree with the manufacturer's assessment, FDA intends to*	☑	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

	continue with the additional Special 510(k) factors.		
	Comments:		
3.	**There is a well-established method to evaluate the change.** *Well-established methods include those used in the previously cleared 510(k), an FDA-recognized consensus standard or FDA guidance document, qualified medical device development tools (MDDTs), are widely available and accepted, or found acceptable through a different premarket submission by the same manufacturer of the predicate.*	☑	☐
	Comments: **(b)(4)**		
4.	**The data be reviewed in a summary or risk analysis format.** *The results from verification and validation associated with design or labeling changes should be able to be placed in a summary or risk analysis format without losing information necessary to support SE. Complete test reports should not be submitted in a Special 510(k). If complete test reports are submitted, FDA intends to assess whether the information can be reviewed in a summary format before converting to a Traditional 510(k).*	☑	☐
	Comments: All results from verification and validation associated with the changes are placed in a summary or risk analysis format.		

Is the submission appropriate for review as a Special 510(k)? *Answer Yes if the change was submitted by the manufacturer of the predicate, well-established methods are available for any performance data necessary, and performance data can be reviewed in a summary or risk analysis format.*

☑ Yes, submission is appropriate for a Special 510(k). Continue checklist below.

☐ No, submission is not appropriate for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

Organizational Elements

Failure to include these items should not result in an RTA designation.

***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☑	☐	Page 2
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☑	☐	
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section*	☑	☐	

	(e.g., 12-1, 12-2…).			
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☑	☐	Page 1 and footer
Comments:				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)
Submission should be designated RTA if not addressed

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☑	☐		
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):					
		a.	Device trade/proprietary name	☑	☐		Page 5 & Attachment 02
		b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☑	☐		Page 5 & Attachment 02
		Comments: CDRH Premarket Review Submission Cover Sheet (Form FDA 3514) is included as Attachment 02					
	3.	Submission contains an Indications for Use Statement with Rx		☑	☐		Page 6 & Attachment 05

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		and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended format (https://www.fda.gov/media/86323/download).*				
		Comments: Indications for Use Statement (Form FDA 3881) is included as Attachment 05				
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*	☑	☐		Page 9 - 10
		Comments:				
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(*l*). *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☑	☐		Page 11 & Attachment 6
		Comments:				
	6.	Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*	☐		☑	N/A
		a. Contains Class III Summary and Certification per 21 CFR 807.87(k). *See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary). Select "N/A" only if submission is not a Class III 510(k).*	☐	☐	☑	N/A
		Comments The NEUROMARK® System is a class II device.				
	7.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR**	☑	☐		Page 5 & Attachment 2 Page 6 & Attachment 03

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		States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).*					
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☐	☐	☑	N/A
		Comments:					
	8.	The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards. Select "N/A" if the submission does not utilize voluntary consensus standards.*		☑		☐	Page 14 & Attachment 02
		a.	The submission cites FDA-recognized voluntary consensus standard(s).	☑		☐	Page 14 & Attachment 02

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			i.	The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,"the basis of such use is included along with the underlying information or data that supports how the standard was used.	☑	☐		Page 14 & Attachment 02 The submission cites general use of standards and all reports as referenced within the submission include data that supports how the standard was used.
		b.	The submission cites non-FDA-recognized voluntary consensus standard(s).		☐		☑	
			i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	☐	☐		
				Comments:				
	Combination Product Provisions – Per 503(g) of the FD&C Act. Select N/A if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.						☑	
	9.	Submission identifies the product as a combination product.			☐	☐		
	10.	The combination product contains as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act. Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.			☐		☐	

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		a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See 503(g)(5)(A)&(C).	☐	☐		
		Comments:					
B.	**Device Description**						
	11.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☑	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above.*	☐	☐	☐	

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			Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.				
		Comments:					
	12.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☑	☐		Pages 9 & 15 and Attachments 12 and 13
		Comments:					
	13.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☑	☐		Page 20
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☑	☐		Page 20
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☐	☐	☑	
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*	☑	☐		Page 16
		Comments:					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	14.	A detailed description of all device modification(s) including rationale for each modification. *When labeling or specific technological characteristics (e.g., materials, dimensions) are unchanged in comparison to the predicate, the submission should clearly state that no changes were made.*		☑	☐		Pages 15-19
		Comments:					
	15.	Device is intended to be marketed with accessories and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.*		☐		☑	
		a.	Submission includes a list of all accessories to be marketed with the subject device.	☐	☐		
		b.	Submission includes a description (as detailed in item 13a., 13b., and 13d. above) of each accessory. *Select "N/A" if the accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☐	
		c.	A 510(k) number is provided for each accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☐	☐		
		Comments:					
C.	**Substantial Equivalence Discussion**						
	16.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is	☑	☐		Page 20

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*				
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☑	☐		Pages 9, 20
		Comments:					
	17.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☑	☐		Page 20
		b.	Technology, including technical specifications, features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing*	☑	☐		Page 20 - 21

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
			technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.					
D.	**Design Control Activities**							
	18.	Design Control Activities Summary includes all of the following:						
		a.	Identification of risk analysis method(s) used to assess the impact of the modification on the device **AND** the results of the analysis.		☑	☐		Page 22-24
		b.	Identification of the device change(s).		☑	☐		Page 22-24
		c.	Identification of all risks associated with each device change, including identification of risks that are considered new because of the change; and		☑	☐		Page 22-24
		d.	Risk control measures to mitigate identified risks (e.g., labeling, verification).		☑	☐		Page 22-24
		e.	Based on the Risk Analysis, an identification of the verification and/or validation activities required to comply with 21 CFR 820.30. This identification includes a summary of test methods (including any protocol deviations), acceptance criteria, results in a summary or risk analysis format (e.g., basic descriptive statistics, where appropriate), and why each is adequate to establish substantial equivalence. If unchanged from a previous premarket submission, the manufacturer references the location of protocols and acceptance criteria by providing a submission and section numbers.		☑	☐		Pages 24 - 29, 31-33, 34-38,39-41 (Tables 5-8, and 10-12)
			i.	For non-standardized test methods only: • A reference to the protocol used for the existing device with an identification of any differences (e.g., protocol, test conditions, pre-defined acceptance criteria, sample size) from the previous 510(k). If protocol changes were made, the results summary describes why the test methods, acceptance criteria, and results	☐	☐	☑	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	Identified in title page and footer ***Page #**
				support SE.				
		f.	A signed statement by the manufacturer's designated individual(s) responsible for design control activities. Both items below must be present to answer "Yes." i. Statement that, as required by the risk analysis, all verification and validation activities were performed by designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. ii. Statement that the submitter has complied and is not currently in violation of the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review, upon request.		☑	☐		Page 24 & Attachment 14
		Comments:						
E.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**							
	19.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).			☑	☐		Page 19 & Attachments 07 - 13
		a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified. *FDA recommends clean and redlined copies be provided.*		☑	☐		Page 19 & Attachments 07 - 13
		Comments:						

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

*Management review of checklist and concurrence with decision required.

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510(K) SUMMARY

Date Prepared: Oct 20, 2022

Submitter Information:
Neurent Medical
1 Oran Point, Main Street
Oranmore, Co. Galway, H91 D7X2
Ireland

Establishment Registration: 3016813690

Contact Information:
Karen E. Peterson
Vice President Clinical, Regulatory & Quality
Neurent Medical
(651) 398-4341
karen@neurentmedical.com

Device Information:

Trade Name:	NEUROMARK® System [K222032]
Common Name:	Radiofrequency Probe
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	GEI
Classification:	Class II
Regulation Number:	21 CFR 878.4400
Predicate Device:	NEUROMARK® System [K212666]

Device Description:
The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis.

The NEUROMARK® System is composed of the NEUROMARK® Device and the NEUROMARK® Radiofrequency (RF) Console.

The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft, and treatment tip. The treatment tip, which is referred to as the End Effector, consists of an array of bipolar electrodes that deliver RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery. The shaft of the device is pre-shaped to aid access and delivery to the nasal cavity but is malleable to allow the user to bend or shape it to accommodate variations in anatomy to access the desired treatment area. The NEUROMARK® Device is operated via handle, slider and activation button. Once in the desired position within the nasal cavity, the operator moves the slider backwards which retracts the outer sheath, deploying the End Effector. Using the activation button, the user initiates a bio-impedance check to assess and confirm contact between the End Effector and the treatment area. Once the System confirms contact has been achieved, a subsequent press of the activation button initiates the RF energy delivery cycle. The NEUROMARK® Device is intended for single use and provided sterile (EO).

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The NEUROMARK® Device is designed for use with the NEUROMARK® Radiofrequency (RF) Console; it includes features to allow compatibility and authentication once connected, via a flexible interface cable, to the Console.

The NEUROMARK® Console delivers, monitors and controls RF energy to the Device. The Console is mounted on an ergonomic mobile stand for ease of use. The Console includes a Graphical User Interface (GUI) which provides operational instructions for the procedure, directs the user to select nasal cavities for treatment, indicates when the device is in contact with tissue and ready to start treatment, provides status of therapy and indicates when the procedure is complete. The NEUROMARK® Console works in conjunction with software.

Indication for Use:
The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

Technological Characteristics:
The NEUROMARK® System (subject device) has the same indications for use and fundamental scientific technology as the predicate NEUROMARK® System [K212666].

The subject device has the same technological characteristics (i.e., principle of operation, basic design, functionality, energy type, biocompatibility, sterile packaging, shelf life, and sterilization) as the predicate device. The Treatment Tip (End Effector) of the subject device has different material and base component construction from that of the predicate device. The subject device has electrodes distributed over 4 proximal leaflets compared to 6 proximal leaflets in the predicate device. In addition, the subject device connector and interface cable was modified to simplify the connection of the device to interface cable.

Substantial Equivalence:
The NEUROMARK® System has the same indications for use and fundamental scientific technology as the predicate device. Evaluation of the impact of the device modifications was completed. No new risks were identified and relevant performance testing was repeated to ensure the subject device still meets intended use, product specifications, and performs similarly to the predicate device.

Performance Data:
Performance testing of the NEUROMARK® System consisted of design verification/validation testing, biocompatibility, software, and electrical and thermal safety testing to support the device modifications listed above. All testing passed and showed that the device meets design specifications and performed as intended.

Conclusion:
In conclusion, the indications for use and technological characteristics are the same as or equivalent to the predicate device. Performance testing has demonstrated that the subject device is as safe and effective and is substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Karen Peterson
Vice President Clinical, Regulatory & Quality
1 Oran Point, Main Street, Oranmore
Galway, Connaught H91D7X2
Ireland

Re: K222032
Trade/Device Name: NEUROMARK System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 28, 2022
Received: July 29, 2022

Dear Karen Peterson:

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

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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,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

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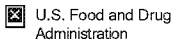
Hi Karen,

We have some suggested edits for your 510k Summary. I think they are relatively minor – please see track changes in this document (given our time constraints I entered the edits myself).

Thanks,
Lindsay

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Ph: 240-402-1462
Email: lindsay.devries@fda.hhs.gov



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(b)(4)

Document Title: (b)(4) e Letter

Revision: (b)(4)

Document Number: (b)(4)

Release Date: 6/30/2022

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DIVISION 510(k) MILESTONE WORKSHEET

(b)(5)

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K222032/S001

NEURENTMedical

July 28, 2022

FDA/CDRH/DCC
JUL 29 2022
RECEIVED

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) - WO66-G609#
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K222032 S001 NEUROMARK® System
Response to FDA Acceptance Checklists of July 18, 2022 and July 26, 2022

Dear Madam/Sir,

This Supplement to the above 510(k) Premarket Notification responds to the FDA requests in the 510(k) Acceptance Checklists of July 18, 2022, and July 26, 2022. We believe the enclosed response addresses all the requests identified by FDA.

In accordance with FDA Guidance 'eCopy Program for Medical Device Submissions', issued April 27, 2020, this cover letter along with an eCopy of the submission is provided.

Neurent Medical considers the information contained in this submission to be proprietary and not intended for public disclosure, except for the 510(k) Summary. Confidentiality is requested in accordance with 21 CFR 807.95.

Thank you for your consideration of the information provided in this submission. If you have any questions, please feel free to contact me by telephone at (651) 398-4341 or by email at karen@neurentmedical.com.

Sincerely,

(b)(6)

Karen E. Peterson
Vice President Clinical, Regulatory & Quality
Neurent Medical
karen@neurentmedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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August 3, 2022</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your submission K222032/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review.

The lead reviewer assigned to your submission is me, Lindsay DeVries. The file is being reviewed in Office of Health Technology 1, Division of Health Technology 1 B. The first line supervisor is the Assistant Director, ENT Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

We will contact you should we require any additional information during the course of the substantive review. FDA aims to apply the least burdensome principles when requesting additional information.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NEUROMARK Radiofrequency (RF) Console Instructions for Use

Neurent Medical Ltd.
1 Oran Point, Main Street,
Oranmore, Co. Galway, Ireland
Phone: +353 91 416812
Email: productfeedback@neurentmedical.com
Website: www.neurentmedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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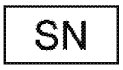
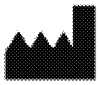
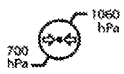
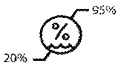
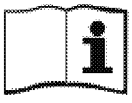
EXPLANATION OF LABELING SYMBOLS

	Alternating Current		Part number
	Date of Manufacture		Lot number
	Type CF defibrillator proof applied part		WEEE Directive Label: Dispose of Properly
	Electrical Hazard (Yellow)		Do not stack more than x packaged assemblies where x in this example is 2
	Do not use if the packaging is damaged		Non-ionizing Radiation
	Caution		Equipotentiality
	Serial Number		CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.
	USB port		Follow Instructions for Use (Pantone blue)
	This end up		Fuse
	Fragile, handle with care		Manufacturer
	Atmospheric pressure range		Temperature range
	Humidity range	GTIN	Global Trade Identification Number
	Store under dry conditions		Protective earth (ground)
	Consult Instructions for Use		MET Certification Mark

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ESSENTIAL INFORMATION ON THE NEUROMARK CONSOLE

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient complications.

INTRODUCTION

The system presented in this user manual consists of the Neurent Medical NEUROMARK Console and associated accessories. This user manual provides a description of the NEUROMARK Console, its controls and displays and instructions for preparation for use. This IFU also supplies other information of importance to the user. Do not operate the system before thoroughly reading this IFU. The NEUROMARK Console is only intended for use with the NEUROMARK Device. Refer to the NEUROMARK Device IFU (IFU-003) for instructions for carrying out a NEUROMARK therapeutic procedure.

INTENDED USE

The NEUROMARK Console is a bipolar radiofrequency (RF) platform intended for connection to the NEUROMARK Device to form the NEUROMARK System. The NEUROMARK System will deliver RF energy to soft mucosal tissue in otolaryngological / ENT procedures.

INDICATIONS

The NEUROMARK™ System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

KNOWN CONTRAINDICATIONS

- None

MEDICAL RISKS AND UNDESIRABLE SIDE-EFFECTS

Potential adverse effects related to the use of radiofrequency energy on tissue in the nasal airway include infection, bleeding, mucosal trauma, mucosal perforation, superficial burns, temporary pain/discomfort, temporary headache, scar formation with increased obstruction, cosmetic deformity, sensory (olfactory) changes at treatment site, septal perforation, worsened eustachian tube function, atrophic rhinitis, bone necrosis or dry nose.

FREQUENTLY USED FUNCTIONS

The following frequently used functions of the NEUROMARK Console have been identified.

- Pressing of the touch screen to select the required nasal cavity on the Console GUI
- Pressing of the NEUROMARK Device hand-switch or via NEUROMARK Console backup RF ON/OFF Button to activate a baseline bio-impedance check
- Pressing of the NEUROMARK Device hand-switch or via NEUROMARK Console backup RF ON/OFF Button to activate a delivery of RF energy.
- Pressing of the GUI touch screen to select options after the RF delivery cycle has stopped.
    - Press “Add Treatment” to treat in the same cavity with leaflets that were not active during the preceding RF Treatment cycle.
    - Press “Change Side” to switch treatment to the other nasal cavity
    - Press “Complete Procedure” option to complete and close the procedure.

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PRODUCT DESCRIPTION

The NEUROMARK Console supports two channels of bipolar RF power delivery which is distributed to up to 12 bipolar channels. RF energy delivery is regulated by power control in all cases. The LCD screen displays the graphical user interface (GUI) for the Console. The operator initiates RF energy delivery by pressing a button on the NEUROMARK Device. Once RF power has been initiated, the delivery sequence of RF is algorithmically controlled. A Power Delivery Indicator LED is included on the front panel of the Console and is illuminated any time RF power delivery over 10mW is occurring. Alerts that occur during RF power delivery are brought to the attention of the operator by an on-screen message accompanied by an audible tone.

When you open the NEUROMARK Console box, you will find:

- NEUROMARK Console
- Mains Power Cord (US)
- Interface Cable for the NEUROMARK Device
- User Manual

The NEUROMARK Console will be used in conjunction with the following accessories, each of which will be packaged separately.

- Cart (includes Mounting Bracket)
- Basket
- Handle
- NEUROMARK Device

GLOSSARY OF TERMS

Term	Definition
FDA	Food and Drug Administration
Mode	A group of states that comprise the machine steps to complete a procedure.
POST	Power On Self Test
RF	Radiofrequency
RFG	Radiofrequency Console
ENT	Ear, Nose and Throat

WARNINGS

The safe and effective use of this system is dependent upon factors under the control of the operator. There is no substitute for a properly trained operating room staff. It is important the operating instructions supplied with the NEUROMARK Console be read and understood before use.

- Read before use: do not operate the NEUROMARK Console before thoroughly reading this manual.
- Risk of Fire: do not use in the presence of flammable anesthetics, other flammable gases, near flammable fluids (such as skin prepping agents and tinctures), flammable objects, or with oxidizing agents. Observe appropriate fire precautions always.
- Risk of Fire: do not use this device in oxygen-enriched atmospheres, nitrous oxide (N2O) atmospheres, or in the presence of other oxidizing agents.
- Risk of RF burns: do not turn RF power on while touching any electrodes.

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- Risk of RF burns to the patient: while using this device during an RF procedure, the patient should not be allowed to come into direct contact with grounded metal objects such as the surgical table frame, the instrument table, etc. The use of antistatic sheeting is recommended.
- Risk of RF burns to the patient: skin-to-skin contact (e.g. between the arms and body of the patient) should be avoided (e.g. by insertion of dry gauze).
- Risk of RF burns: failure of the Console or accessories could result in an unintended increase of output power.
- Care should be taken to avoid the danger of ignition of endogenous gases.
- RF energy can produce unintended neuromuscular stimulation during ablation. Appropriate precautions, including the use of lower power settings and continuous monitoring of the patient during treatment, should be taken to minimize the risk of patient injury.
- Interference with other equipment: use only with approved devices and accessories. Use of accessories other than those specifically approved by Neurent Medical for use with the NEUROMARK Console may result in increased electromagnetic emissions or decreased electromagnetic immunity.
- Interference with other equipment: use of electrosurgical generators on patients with internal or external pacemakers, implantable defibrillators, or monitoring equipment may be affected. Qualified advice should be obtained as necessary to minimize the risk of injury from implanted device malfunction.
- Interference with other equipment: use of electrosurgical generators on patients with conductive implants can cause the implants to heat up and damage tissue. Qualified advice should be obtained as necessary to minimize the risk of injury from conductive implant heating.
- Interference with other equipment: during RF output, the conducted and radiated electrical fields may interfere with other electrical medical equipment. If interference with an instrument outside of the NEUROMARK System is suspected, move the instrument and its cables away from the NEUROMARK System.
- Risk of electric shock: to avoid the risk of electric shock, the NEUROMARK Console must only be connected to supply mains with a protective earth. Do not use extension cords or three-prong to two-prong adapters. The mains power cord assembly should be periodically checked for damaged insulation or connectors.
- Risk of electric shock: no modification of this equipment is allowed.
- Risk of electric shock: the NEUROMARK Console is not intended for use with a multiple portable socket outlet.
- Proper device use: do not operate the device if the display area has been damaged or if the screen is cracked or broken. Ship the unit back to the manufacturer.
- Proper device use: Inspect the Extension Cable for damage prior to use. Do not operate the device if the Extension Cable is damaged. Return the unit to the manufacturer.
- Proper device use: do not operate the device if audible tones are not heard for each key press despite increasing the audio volume.
- Proper device use: the LCD, LEDs, and the audible tones will be cycled during Power-On-Self-Test (POST) and should be observed before using the device.
- Proper device use: only use in the configuration as shown in this document.
- Storage: store the Console in accordance with the environmental specifications provided in this document.
- Do not touch the Console and the patient simultaneously.
- Do not start the Console with a USB device installed in the front panel USB port.
- Non-Sterile: the Console, Cart, and Extension Cable are non-sterile and should be placed outside the sterile field. Do not attempt to sterilize the Console, Cart, or Extension Cable.
- Storage: store the Console and Extension Cable at the same temperature and in accordance with the environmental specifications provided in this document.

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PRECAUTIONS

- Do not activate the Console until the probe is properly positioned in the patient.
- The cover of the Console should not be removed. Doing so can result in an electrical shock. For service, contact the manufacturer.
- The Console does not require continuous activation of the device activation button to deliver RF. Always monitor the activation indicator or tone during RF output to determine delivery state.
- The activation tone and light are important safety features. Do not obstruct the activation light. Do not disable the activation audible tone.
- Do not wrap instrument cable around metal objects. Wrapping cables around metal objects may induce hazardous currents.
- The surgical electrode cable should be positioned to avoid contact with the patient or other leads. Unused electrodes should be stored in a location isolated from the patient.
- Perform regular inspections of all accessories for damage to insulation, including electrosurgical cables and probes.
- Only recommended cabling should be used with the Console.
- Use of smoke plume extraction is recommended to minimize the risk of surgical smoke inhalation by operator.
- For information on the connection and disconnection of detachable parts and accessories, refer to the IFU for the corresponding parts and accessories.
- Care should be taken to avoid the danger of ignition of endogenous gases.
- The Console needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this IFU.
- Electronic equipment, including portable and mobile RF communications equipment, can affect the operation of the Console. Operating non-essential equipment in the vicinity of the Console should be avoided. If interference is suspected, the responsible equipment and associated cables should be moved away from the Console.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.
- The Console should not be used adjacent to or stacked with other equipment outside of its pre-set configuration. If the Console must be operated adjacent to or stacked with other equipment outside of this configuration, the Console should be observed to verify normal operation in that configuration.
- When the Console and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating high frequency current limiting devices are recommended.
- If the Console is stored in an environment that is outside of room temperature, an acclimation period of at least 2 hours is required.
- Ensure that all cabling is located at least one inch from the Console's touchscreen during Console operation.
- Multiple power cords may be supplied with the Console. Select the power cord that is configured for your mains supply.
- The Console is not specified for use with a Neutral Electrode.

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DIRECTIONS FOR USE

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to properly follow instructions may lead to improper functioning of the device and result in patient injury.

The NEUROMARK Console consists of the following components.

Description	Model Number
Console	010-00089-000
Mains Power Cord (US)	610-00001-000
Interface Cable for the NEUROMARK Device	600-00254-000
NEUROMARK Device	FS-004-00
Cart (includes Mounting Bracket)	FLP-0001-61
Basket	RS-0001-24
Handle	RS-0004-18

ASSEMBLING THE MOUNTING BRACKET

Follow the Cart Instructions for Use for mounting bracket assembly instructions.

PREPARING THE CART FOR USE

1. Lock the cartwheels prior to mounting. Depress the tab on the wheels to lock. To unlock the wheels, flick the tab up on both wheels. When locking the cartwheels, ensure that one locked wheel is positioned under the handle and in line with the cart pole to prevent unintended movement.
2. Do NOT adjust the position of the mounting brackets on the Cart.
3. Ensure the shelf surface is clear of items.

PREPARING THE CONSOLE FOR USE

4. Inspect the Console for any signs of physical damage to the display, metal trim, or rear panel. Also ensure that all Console labels are present and legible. If any physical damage is found, DO NOT USE THE CONSOLE. CONTACT manufacturer for a replacement. Manufacturer must approve all returns.
5. Inspect the power cord(s) for damage.
6. The Console shall be placed on a mounting Cart using the provided mounting bracket. Do NOT use the Console without mounting on a compatible Cart. If the Cart has not been assembled yet, follow the Cart Instructions for Use for assembly instructions.
7. Ensure nothing is connected to the Console prior to mounting.

MOUNTING THE CONSOLE

8. Lift the Console such that the Console mounting holes are level with the holes in the Cart mounting bracket.
9. Use the four (4) screws provided with the Cart to attach the Console to the mounting bracket. Ensure the Console is secure.
10. Do NOT adjust the position of the mounting brackets on the Cart.
11. Do NOT obstruct the vents on the underneath of the Console. Under continuous use for extended periods of time, it is normal for the outer housing to be warm to the touch.

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POWERING ON THE CONSOLE

12. Connect the RFG power cord to the AC Power Inlet on the Console and the other end to a wall outlet. Position the Console such that the power supply connection is easily accessible as a means of disconnecting power from the Console.
13. Locate the AC Mains Switch on the rear panel of the Console. Flip the switch to **I** to turn the Console on. During start up, the LCD, LEDs, and audible alarm will by cycled and should be observed before using the Console.

STARTING A PROCEDURE

14. Follow the instructions for use provided with the NEUROMARK Device to prepare the therapeutic device for an ablation procedure. NOTE: if interference with an instrument outside of the system is suspected, move the instrument and its cables away from the system.
15. Follow the on-screen instructions on the Console to start a procedure.

ADJUSTING CONSOLE SETTINGS

To enter Console Settings, press the Settings icon on the top right of the screen when RF delivery is not active.

- Press the increase or decrease slider next to speaker volume to adjust audible tone volume.
- Press the increase or decrease slider next to display brightness to adjust display brightness.
- To download therapy logs, insert a USB memory key into the front panel USB port and press the Download Logs button.
- To calibrate the touchscreen, press the Touchscreen Calibration button and follow the instructions provided on the screen. If the touchscreen is mis calibrated, power cycle the unit (OFF-ON) and press and hold the touchscreen for 2 seconds once "AdvantageRF" is displayed on the splash screen.

SHUTDOWN PROCEDURE

- Turn off the mains power using the AC Mains Switch on the rear panel of the Console. Flip the switch to the "O" position to turn off. Ensure the LCD is off.
- Disconnect the Console power cord from the mains and the AC Power Inlet on the Console.

CONSOLE CLEANING AND DISINFECTION INSTRUCTIONS

- Use a solution of 70% isopropyl alcohol (IPA) and a damp cloth to clean the NEUROMARK Console surfaces and cabling. The NEUROMARK Console cannot be sterilized. Do not allow fluids to enter the chassis.
- Do not spray or pour liquids directly onto the Console.
- Flammable agents used for cleaning or disinfecting, or as solvents or adhesives, should be allowed to evaporate before use. Non-flammable agents should be used for cleaning and disinfection wherever possible.

CONSOLE MAINTENANCE SCHEDULE

- The Console verifies calibration integrity during Power-On Self-Test (POST). Maintenance is not required.
- For cleaning and disinfection instructions, refer to the previous section.

DISPOSAL INSTRUCTIONS

- Do not dispose. Return to Manufacturer.

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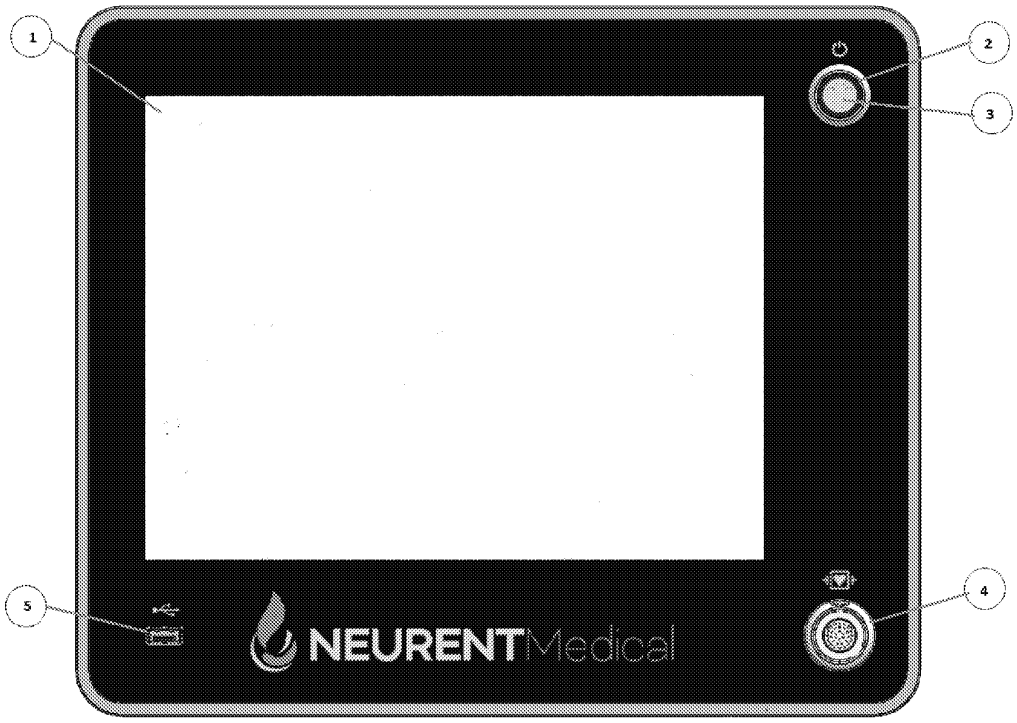
USER INTERFACE

Front Panel Controls and Connections



1. Touchscreen Window: displays messages and allows the Operator to interact with the device through the touchscreen. If a system fault occurs, the Console will enter Fault state. Power to the system must be cycled (OFF-ON) to attempt recovery from a system fault.
2. Backup RF ON/OFF Indicator: LED around the RF ON/OFF button indicating if RF is being delivered. The indicator is on and blue during RF delivery and off when RF is not delivered.
3. Backup RF ON/OFF button: toggles the RF output on if the system is in Measure Mode, or off if the system is in RF delivery Mode.
4. RF Output Connection: patient-isolated connection for attachment of the Console Interface Cable
5. Front USB Port allows for a USB flash drive to be connected to the front panel for updating software and downloading logs.
   CAUTION: only USB memory devices should be used in the front panel USB port.

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Rear Panel Controls and Connections

1. Fuse Drawer: houses the fuse and allows for AC input voltages of 100-240 V.
2. AC Mains Switch: controls the AC power input.
3. AC Power Inlet: AC power cord is connected to the inlet to supply power to the system.
4. Equipotential Ground Connection: This connector is attached to the chassis/earth ground and is intended for earth reference connection in environments where equipotential ground cabling is used.
5. Device Labels: indicate the unit model number and serial number.
6. Foot-switch Connection (NOTE: This port will be unused)
7. Back USB Port allows for a USB flash drive to be connected to the rear panel for updating software and downloading logs. The Front USB Port will be the primary mode of access **CAUTION:** only USB memory devices should be used in the front panel USB port.

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TECHNICAL SPECIFICATIONS

System Classification

The NEUROMARK System is classified per IEC 60601-1:2005 as shown in the table below.

Item	System Classification
Protection against Electric Shock	Class I
Applied Part: NEUROMARK Device (FS-004-00)	Type CF defibrillator proof
Mode of Operation	Continuous
Ingress Protection	IPX0
Methods of Sterilization	Console: N/A NEUROMARK Device: EO
Suitability for Use in an Oxygen Rich Environment	Not suitable

Compliant Standards

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012
- IEC 60601-2-2:2017 (Sixth Edition)
- IEC 62304:2015 (Edition 1.1)
- IEC 60601-1-2:2014 (Fourth Edition)
- IEC 60601-1-6:2010, AMD1:2013 (Edition 3.1)
- IEC 62366-1:2015 (First Edition)

Impedance Measurement

- Range 40 to 2000 Ω with 1 Ω resolution.
- Low Power Impedance Measurement delivers < 10.0 mW as averaged over any 1 s period.
- Low Power Impedance Measurement utilizes the same frequency as the RF output.
- No greater than 25 VRMS is applied to the RF load during Low Power Impedance Measurement.
- Low Power Impedance Measurement provides impedance reading at least once every 0.1 s.

RF Output

Frequency:	465.1 kHz ± 3%
Waveform:	Quasi-sinusoidal voltage waveform with harmonic content < -15 dBc
Maximum power:	40 VA (into an impedance range of 40 Ω - 2000 Ω)

Outside this range, the Console reduces available power to comply with specified voltage and current limits. Applied part of patient circuit is not referenced to earth at high frequency.

The maximum output of 40 VA is restricted by:

Maximum Voltage:	130 VRMS
Maximum current:	1.0 ARMS
Phase Angle:	Between -30º (capacitive) and +30º (inductive)

Measurement Accuracy (at time of manufacture)

Power:	
Impedance = 40 – 99 Ω	± 10% or ± 1 W, whichever is greater
Impedance = 100 – 500 Ω	± 5% or ± 0.2 W, whichever is greater
Impedance = 501 – 1000 Ω	± 8% or ± 1 W, whichever is greater
Impedance = 1000 – 2000 Ω	± 15% or ± 1 W, whichever is greater

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Impedance:	
40 – 99 Ω	± 10% or ± 5 Ω, whichever is greater
100 – 1000Ω	± 8%
1000 – 2000Ω	± 15%

Hardware Shutdown Limits

Measured RF Power:	> 40 W

Mechanical Specifications

Size:	336mm x 282mm x 103mm
Weight:	17lb (7.7kg) maximum (console only)
Moisture protection rating:	IPX0 (ordinary, per IEC601)

Environmental Specifications

Operating Temperature:	10 °C to 40 °C
Operating Relative Humidity:	30% to 70% non-condensing
Transport and Storage Temperature:	-20 °C to 60 °C
Transport and Storage Relative Humidity:	20% to 95% non-condensing
Altitude:	Up to 3000m

All system components must undergo a two -hour acclimation period at 25 °C +/- 3 °C prior to use after exposure to the storage environment.

Fuses

Replace mains fuses as marked: 5 A / 250 V, High breaking capacity, T-lag, 5X20 mm
When replacing fuses, ensure the integrity of the new fuses by inspecting for damage that could affect the function of the fuse. Use a precision slot drive screwdriver to remove the fuse drawer. Replace the fuses and close the fuse drawer.

Line Input Ratings

The Console operates from an AC source ranging from 100 to 240 VAC, 50/60 Hz, 2.5A.

Rated Accessory Voltage

The rated voltage for the Extension Cable and NEUROMARK device is 130 VRMS.

Output Power Graphs

Power cannot be delivered below 40 ohms.

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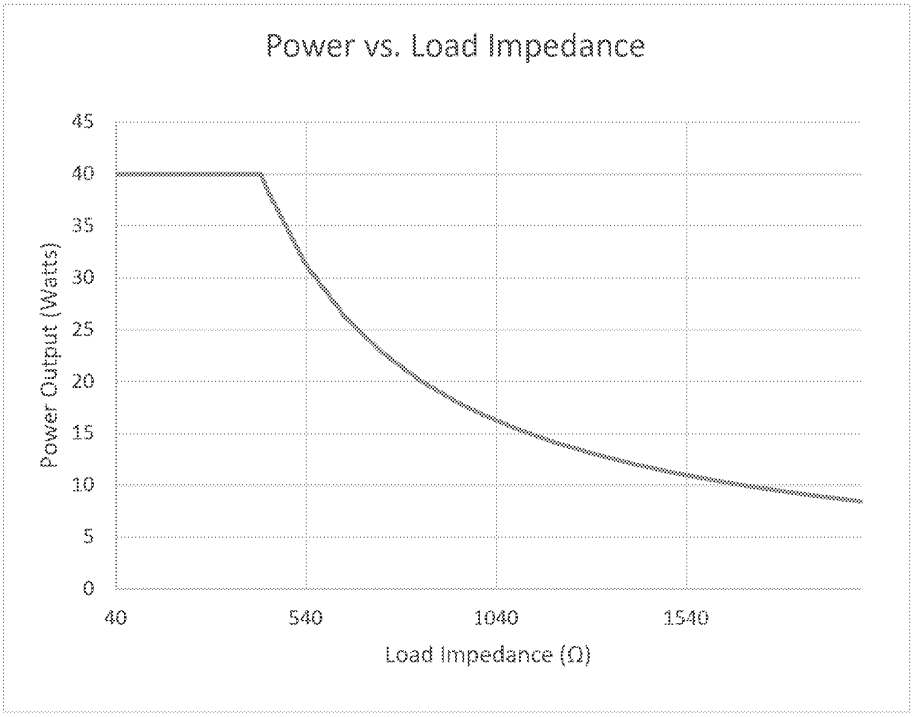

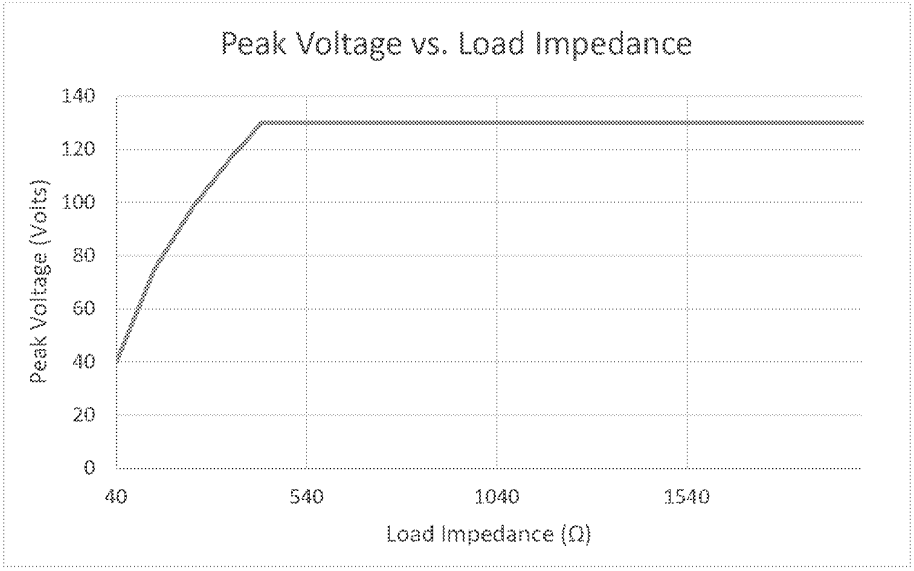

Alert/Error Tones

- When an Alert indication is raised, the Console will sound the Alert Tone.
- When an Error indication is raised, the Console will sound the Error tone.
- An Alert tone consists of a single Alert Pulse.
- An Error tone consists of a single Alert Pulse repeated every 4 to 5 seconds.
- Alert Pulse volumes are always greater than 40 dBA and less than 90 dBA.

Alert Condition Logging

The Console logs the occurrence and identity of alert conditions. The log file is maintained when the alert is acknowledged, and the system is powered down.

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Fault State

If a non-recoverable fault is encountered, the Console will enter a Fault State. The Fault State will display a fault code and basic instructions to the operator. Follow the instructions provided on screen. An Error tone will play in the Fault State. Mains power to the Console must be cycle (OFF-ON) to attempt recovery from a fault.

EMC Specifications (Emissions)

Table 1: Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

EMC Specifications (Immunity)

Essential performance was shown to be maintained for all levels of electromagnetic immunity testing. Essential performance for this system includes accurate temperature measurement during lesion delivery, and accurate measurement of RF power levels.
A degradation in essential performance will generally always be prevented by an alert or error associated with that function. In the unlikely event that an alert or error does not prevent degradation of essential performance by an electromagnetic disturbance, one or more aspects of essential performance, as defined above, may be impacted.

Table 2: Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines Both at 100kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/output lines Both at 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.

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The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Surge IEC 61000-4-5	For power supply lines: ±0.5kV and ±1kV line(s) to line(s) ±0.5kV, ±1kV, and ±2kV line(s) to ground For signal input/output ports: ±2kV line(s) to ground	For power supply lines: ±0.5kV and ±1kV line(s) to line(s) ±0.5kV, ±1kV, and ±2kV line(s) to ground For signal input/output ports: ±2kV line(s) to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles 0% UT for 250/300 cycles	0% UT for 0.5 cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles 0% UT for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Console requires continued operation during power mains interruptions, it is recommended that the Console be powered from an uninterruptible power supply.
Note: UT is the AC mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V ISM bands between 0.15 MHZ and 80 MHZ 80% AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V ISM bands between 0.15 MHZ and 80 MHZ 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz Specific communication	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz Specific communication	Recommended separation distance: d = [1.17] √P d = [1.17] √P 80 MHz to 800 MHz P = [2.33] √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the

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The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
	frequencies tested per table 6	frequencies tested per table 6	transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: at 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones, and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System including cables or any of its components are used exceeds the applicable RF compliance level above, the System including cables should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System including cables. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 3: Enclosure port immunity levels to RF wireless communications equipment

Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	GM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870	800 – 960	GSM 800/900,	Pulse modulation	2	0.3	28

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
930		TETRA 800, iDEN 820, CDMA 850, LTE Band 5	18 Hz			
1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the Console including cables.

The Console (including cables) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Console (including cables) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Console including cables as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d = [1.17]\sqrt{P}$	80kHz to 800MHz $d = [1.17]\sqrt{P}$	800kHz to 2.5GHz $d = [2.33]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: at 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note 2: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
07/08/2022	(b)(4)	

SECTION A — TYPE OF SUBMISSION

PMA & PDP
- ☐ Original
- ☐ Modular Submission
- ☐ Amendment
- ☐ Report (annual or PAS)
- ☐ Report Amendment
- ☐ Other:
  - ☐ Premarket Report (reprocessed SUD)
  - ☐ Licensing Agreement

PMA/PDP Supplement
- ☐ 180 day - PAS protocol or labeling change, location change, trade name change
- ☐ 180 day - Design or labeling change
- ☐ Special CBE
- ☐ Panel Track
- ☐ 30-day Notice
- ☐ Real-time Review
- ☐ Amendment to PMA/PDP Supplement

510(k)
- ☒ Original Submission:
  - ☐ Traditional
  - ☒ Special
  - ☐ Abbreviated
  - ☐ 3rd Party Traditional
  - ☐ 3rd Party Special
  - ☐ 3rd Party Abbreviated
  - ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application)
- ☐ Amendment
- ☐ Supplement

CLIA

CLIA Categorization Record (CR)
- ☐ Original
- ☐ Amendment

CLIA Waiver by Application (CW)
- ☐ Original
- ☐ Amendment
- ☐ Supplement

Q-Submission
- ☐ Pre-Submission
- ☐ Informational Meeting
- ☐ Submission Issue Meeting
- ☐ Day 100 Meeting
- ☐ Agreement Meeting
- ☐ Determination Meeting
- ☐ Study Risk Determination
- ☐ Other *(Specify below)*

IDE
- ☐ Original IDE:
  - ☐ Amendment to Original IDE
- ☐ Supplement:
  - ☐ Amendment to Supplement
- ☐ Report:
  - ☐ Amendment to Report

HDE
- ☐ Original Submission
- ☐ Amendment to Original
- ☐ Report
- ☐ Report Amendment
- ☐ HDE Supplement:
  - ☐ 75-day Supplement
  - ☐ 30-day Notice
  - ☐ Special CBE
  - ☐ Amendment to Supplement

Class II Exemption Petition
- ☐ Original Submission
- ☐ Additional Information

Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment
- ☐ Report

De Novo
- ☐ Original:
  - ☐ Direct
  - ☐ Post-NSE
- ☐ Amendment
- ☐ Supplement

Pre-Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment

Other Submission
- ☐ 513(g)
- ☐ Appeal
- ☐ Other *(Briefly describe submission below)*

Expanded Access to Devices
- ☐ Compassionate Use Request **NOT associated with an IDE**
- ☐ Follow-up Report for Compassionate Use **NOT associated with an IDE**
- ☐ Emergency Use Follow-up Report **NOT associated with an IDE**

SECTION B — APPLICANT / SPONSOR

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Neurent Medical		3016813690
Street Address		**City**
1 Oran Point, Main Street, Oranmore		Galway
State/Province	**ZIP/Postal Code**	**Country**
Connaught	H91D7X2	Ireland

Contact Name	Contact Title
Karen E Peterson	Vice President Clinical, Regulatory & Quality
Division Name *(if applicable)*	**Phone Number *(including area code)***
	(651) 398-4341
Fax Number *(including area code)*	**Contact Email Address**
	karen@neurentmedical.com

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SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section C items, please click on the button to the right. May be repeated as needed. Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

- ☒ Adults Only (greater than 21 years of age)
- ☐ Adults and Pediatrics
- ☐ Neonate/Newborn (birth through 28 days)
- ☐ Infant (from 29 days to 2 years of age)
- ☐ Child (from 2 years to 12 years of age)
- ☐ Adolescent (from 12 years to 18 years of age)
- ☐ Transitional Adolescent A (18 through 21 years of age)
- ☐ Transitional Adolescent B (18 through 21 years of age)
- ☐ Other *(Specify below)*

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	NEUROMARK® System
2	
3	
4	
5	

Common/Generic Name *(Include if no Trade Name)*
Electrosurgical cutting and coagulation device and accessories

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions *(regardless of outcome)* or state no prior submission in box 1.

1 No prior submissions	2	3
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) *(when applicable) (If more than one, please separate with commas.)*

GEI

C.F.R. Section *(If applicable)*	Classification Panel/Medical Specialty
21 CFR 878.4400	General & Plastic Surgery

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE

☐ New Device
☐ STED

☐ Post-approval Study Protocol

☐ HDE Request for Annual Distribution Number (ADN)

☐ Change in Design, Component, or Specification:
- ☐ Software/Hardware
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other *(Specify below)*

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post-approval Study

☐ Process Change:
- ☐ Manufacturing
- ☐ Packaging
- ☐ Sterilization
- ☐ Vendor/Supplier Change
- ☐ Other *(Specify below)*

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ PAS update
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other *(Specify below)*

☐ Amendment:
- ☐ Withdrawal
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Address
- ☐ Request for Extension
- ☐ Response to FDA Correspondence
- ☐ Other *(Specify below)*

☐ Bundle Submission -- *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

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SECTION H2 REASON FOR APPLICATION – IDE

☐ Original IDE

☐ Supplement:
- ☐ New Study/New Protocol
- ☐ Change in Correspondent
- ☐ Change in Manufacturer
- ☐ Change in Sponsor
- ☐ Change in Design
- ☐ Change in Informed Consent
- ☐ Change in Manufacturing
- ☐ Change in Protocol
- ☐ 5-Day Notice – Device or Manufacturing
- ☐ 5-Day Notice – Protocol
- ☐ Compassionate Use Request (under an IDE)
- ☐ Live Case Request
- ☐ Request Deviation from Protocol
- ☐ Expansion of Study (Study/Sites)
- ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter

Supplement *(Continued)*
- ☐ Request for Waiver
- ☐ IRB Certification
- ☐ Request for CMS Recategorization
- ☐ Study Resumed
- ☐ Study Suspension
- ☐ Other *(Specify below)*

☐ Report:
- ☐ Adverse Effect
- ☐ Final, Study Completed
- ☐ Annual Progress
- ☐ Interim Progress
- ☐ Semiannual Investigator List
- ☐ Failure to Obtain Informed Consent
- ☐ Compassionate Use Follow-up
- ☐ Emergency Use
- ☐ Live Case Follow-up
- ☐ Completion of Patient Enrollment
- ☐ Completion of Patient Follow-up
- ☐ Other *(Specify below)*

☐ Amendment to Original IDE:
- ☐ Amendment Before Final Decision
- ☐ Response to Refuse to Accept
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Other *(Specify below)*

☐ Amendment to Supplement:
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

☐ Amendment to Report:
- ☐ Response to Deficiency Letter
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

SECTION H3 REASON FOR SUBMISSION – Q-SUBMISSION

☐ Pre-Submission:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Submission Issue Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Additional Information

☐ Change in Legal Entity:
- ☐ Change in Correspondent
- ☐ Change in Sponsors
- ☐ Change in Manufacturer
- ☐ Other *(Specify below)*

☐ Agreement Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Determination Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Informational Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-Con

☐ Other *(Specify)*:

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SECTION H4 REASON FOR SUBMISSION – 510(k)

- [x] Original
- [ ] Withdrawal of Original
- [ ] Amendment Before Final Decision:
  - [ ] Change in Ownership
  - [ ] Change in Correspondent
  - [ ] Withdrawal
- [ ] Amendment After Final Decision
- [ ] Supplement:
  - [ ] Response to Refuse to Accept (RTA)
  - [ ] Response to Additional Information Request
  - [ ] Withdrawal
- [ ] Reprocessed SUD
- [ ] Corrective Action
- [ ] STED
- [ ] Third Party *(Complete Section C)*
- [ ] Other Reason *(Specify)*:

Information on devices to which substantial equivalence is claimed *(If known)*

	510(k) Number	*Trade Name*	*Submitter*	*Product Code*
Primary Predicate (A)	K212666	NEUROMARK® System	Neurent Medical	GEI
Predicate or Reference Device (B)				

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed. Add Device Information

SECTION H5 DE NOVO SUBMISSIONS

- [ ] Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:
- [ ] Withdrawal

SECTION H6 REASON FOR APPLICATION – CLIA

Includes CLIA Parent Document number, CR number, or CW number.

- [ ] **CLIA Categorization Record (CR):**
  - [ ] CLIA Categorization of marketed device (include marketing submission number)
  - [ ] CLIA Categorization of device exempt from premarket review
  - [ ] Additional information regarding an open CR (include CR number)
- [ ] **CLIA Waiver by Application (CW):**
  - [ ] Request for CLIA Waiver by Application for marketed device (include marketing submission number)
  - [ ] Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
  - [ ] Response to FDA correspondence
  - [ ] Additional information regarding an open CW (include CW number)
- [ ] **Other Reason** *(Specify)*

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SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.	FDA Document Number *(if known)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager/Relabeler

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address

Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address

Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section I items, please click on the button to the right. May be repeated as needed. Add Section I

SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use,* Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use,* Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

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Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	5-40	General Use	*If General Use,* Deviation? No	ISO 14971 Medical devices - Application of risk management to medical devices	Section 13.1 Page 22
2 X	19-4	General Use	*If General Use,* Deviation? No	IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Section 17 Page 39
3 X	6-389	General Use	*If General Use,* Deviation? No	IEC 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high fr	Section 17 Page 39
4 X	2-258	General Use	*If General Use,* Deviation? No	ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Section 15 Page 32
5 X	N/A	General Use	*If General Use,* Deviation? No	(b)(4)	Section 14 Page 30
6 X	14-408	General Use	*If General Use,* Deviation? No	ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	Section 14 Page 31

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

SECTION K UTILIZATION OF CDRH GUIDANCE DOCUMENTS

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at ***http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm***.

Entries for Utilization of CDRH Guidance Documents

	Title of Guidance Document
1 X	

To add another row for Section K, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Document

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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Hello Lindsay,

Thank you for the requested modification to the 510(k) Summary. (b)(4)

(b)(4)

Attached is a redline copy and a clean copy of the updated 510(k) Summary.

Thanks much,

Karen

From: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>

Sent: Thursday, October 20, 2022 9:29 AM

To: Karen Peterson <karen@neurentmedical.com>

Cc: k222032@docs.fda.gov

Subject: K222032: 510k edits

Importance: High

Hello Karen,

I have a requested modification to your 510(k) Summary. (b)(4)

(b)(4)

Please send me a modified 510(k) Summary by COB tomorrow, Friday October 21, 2022. If there is a time issue, please let me know.

Thanks,

Lindsay

Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

[U.S. Food and Drug Administration]<http://www.fda.gov/>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2024-2211; Released by CDRH on 09-09-2024

Yes, that is fine if you concur. I will let you know if there is anything else. Thanks!

From: Karen Peterson <karen@neurentmedical.com>
Sent: Wednesday, October 26, 2022 12:28 PM
To: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>
Cc: k222032@docs.fda.gov
Subject: [EXTERNAL] Re: K222032 510k Summary

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Lindsay,
These look fine to me.
Let me know if this email response is all you need from me.
Thanks,
Karen

Sent via the Samsung Galaxy S9+, an AT&T 5G Evolution capable smartphone
Get Outlook for Android

From: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>
Sent: Wednesday, October 26, 2022 10:03:18 AM
To: Karen Peterson <karen@neurentmedical.com>
Cc: k222032@docs.fda.gov <k222032@docs.fda.gov>
Subject: K222032 510k Summary

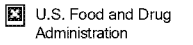
Hi Karen,

We have some suggested edits for your 510k Summary. I think they are relatively minor – please see track changes in this document (given our time constraints I entered the edits myself).

Thanks,
Lindsay

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Ph: 240-402-4462
Email: lindsay.devries@fda.hhs.gov



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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K222032 Date Received by DCC: July 11, 2022

Lead Reviewer: Lindsay DeVries, Au.D., Ph.D.

Center: CDRH Office: OHT 1 Division: DHT1B

Decision:

○ Accept. If Accept, notify submitter.

◉ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below*.	☐	☒	☐
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments: This file was converted from a Special to Traditional 510(k).			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended* format (https://www.fda.gov/media/86323/download).	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a Class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☐	☐	☒		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☒		☐	☐	
a) Submission includes a list of all accessories to be marketed with the subject device.	☒	☐			
b) Submission includes a description (as detailed in item 14(a), 14(b) and 14(d) above) of each accessory.	☐	☐	☒		
c) A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐			
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☐		☒		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☐	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☒	☐	☐		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☐	☐	☒		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☐	☐	☒		
24) If the device and/or accessories, if applicable, are provided sterile:			☐	☐	
a) Sterilization method is stated for each device (including dose for radiation sterilization).	☒	☐			
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	☒	☐			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	☒	☐	☐		
d) Sterility Assurance Level (SAL) is stated.	☒	☐			
e) Submission includes description of packaging.	☒	☐			
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	☐	☐	☒		
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☒	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☒		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☐		☒		
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☐		☒	☐	
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☒	☐	☐	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of colorants/additives, if present.	☒	☐		☐	

Questions? Contact FDA/CDRH/CCE/PIP at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☐	
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☐	☒		☒	
Comments:	(b)(4)				

H. Software

Submission states that the device: (one of the below must be checked)					
☒	Does contain software/firmware				
☐	Does not contain software/firmware				
☐	Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)				
☐	Software/firmware information not needed for this device (e.g., surgical suture, condom)				
☐	Software/firmware information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes a statement of software level of concern and rationale for the software level of concern.	☒	☐		☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
34) All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☐	☒		☒	
Comments:	(b)(4)				

I. Cybersecurity

Submission states that the device: *(one of the below must be checked)*		☐		☒	
☐	Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)				
☐	Does not contain external interfaces as described above				
☒	Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)				
☐	Cybersecurity information not needed for this device (e.g., surgical suture, condom)				
☒	Cybersecurity information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
Comments:	(b)(4)				
35) All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. **OR** Submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☐	☒		☒	
Comments:	See above comment.				

J. Electrical Safety and EMC

Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☒	Does require electrical safety evaluation				
☐	Does not require electrical safety evaluation				
☐	Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)				
☐	Electrical safety information not needed for this device (e.g., surgical suture, condom)				
☐	Electrical safety information is needed or need unclear				

Questions? Contact FDA/CDRH/OCE/DID at CDRH_FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
36) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does require EMC evaluation					
☐ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
37) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☐	☒	☐	☒	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☐	☒			
Comments:	(b)(4)				
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☐		☒	☐	
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☒	☐	
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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Digital Signature Concurrence Table

Reviewer Sign-Off	Lindsay A. Devries -S 2022.07.26 19:55:56 -04'00'
Management Sign-Off (digital signature optional)*	

* Management review of checklist and concurrence with with decision required.

FDA

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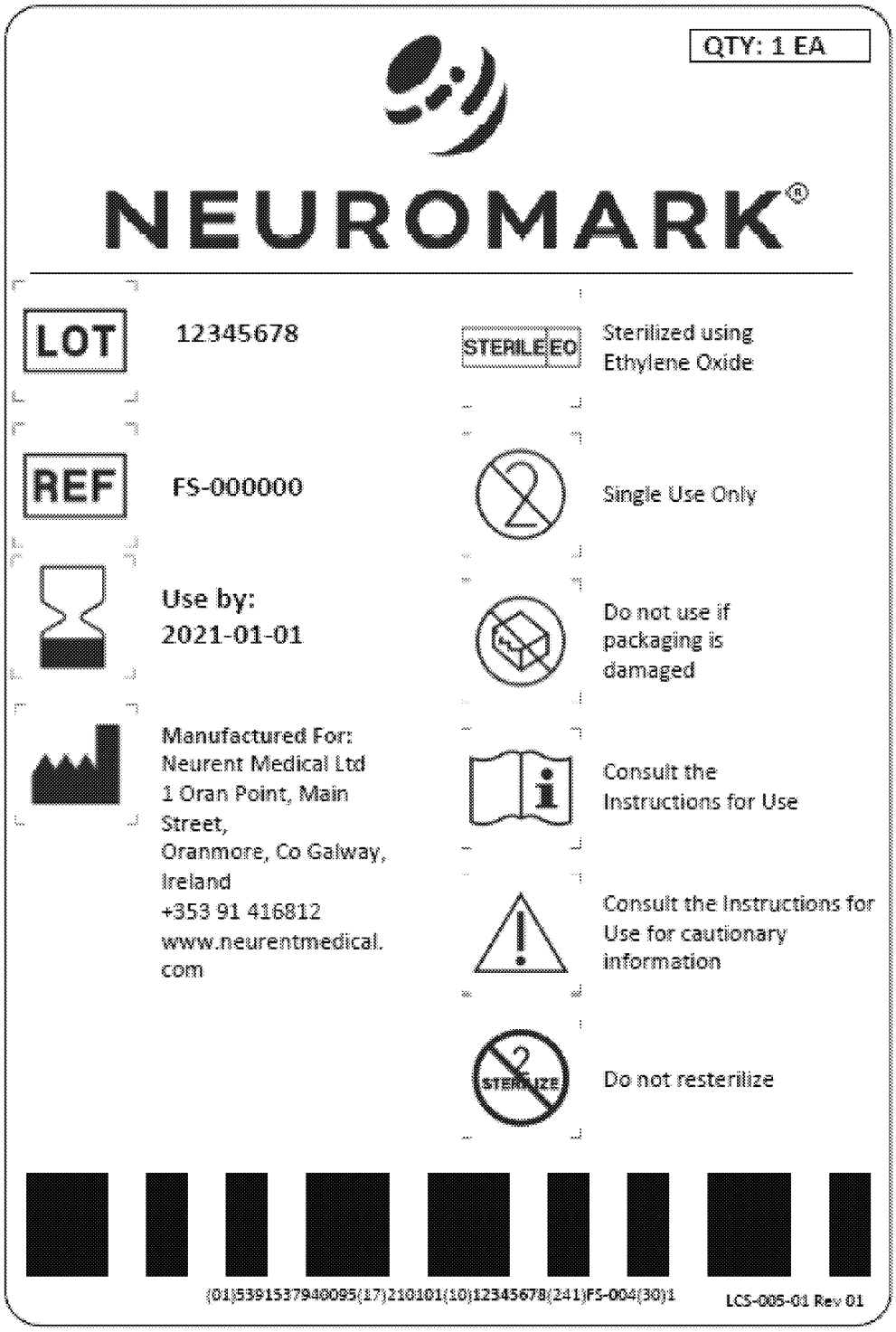
Attachment 07 – Subject Device Packaging Label



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)
The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K222032/S001 Date Received by DCC: July 29, 2022

Lead Reviewer: Lindsay DeVries, Au.D., Ph.D.

Center: CDRH Office: OHT 1 Division: DHT1B

Decision:

◉ Accept. If Accept, notify submitter.

○ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ○ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

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3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below*.	☐	☒	☐
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or class I/II and 510(k) exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *See recommended format (https://www.fda.gov/media/86323/download).*	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☐		☐	☐	
a) Submission includes a list of all accessories to be marketed with the subject device.	☒	☐			
b) Submission includes a description (as detailed in item 14(a), 14(b) and 14(d) above) of each accessory.	☒	☐	☐		
c) A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐			
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling).	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☐		☒		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☐	☐	☐		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☐	☐	☐		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☒	☐	☐		
24) If the device and/or accessories, if applicable, are provided sterile:			☒	☐	
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☐	☐	
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☐		
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☐	☐	☐		
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☐		☒		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☐		☒	☐	
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☒	☐	☐	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☐	
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does contain software/firmware					
☐ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes a statement of software level of concern and rationale for the software level of concern.	☒	☐		☐	
34) All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☐ Does not contain external interfaces as described above					
☒ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☒ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does require electrical safety evaluation					
☒ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)		☐		☒	
☐ Does require EMC evaluation					
☒ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
Comments: (b)(4)					
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☐		☒	☐	
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☒	☐	
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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Digital Signature Concurrence Table

Reviewer Sign-Off	Lindsay A. Devries -S 2022.08.01 13:52:37 -04'00'
Management Sign-Off (digital signature optional)*	

* Management review of checklist and concurrence with with decision required.

Hi Lindsay,
These look fine to me.
Let me know if this email response is all you need from me.
Thanks,
Karen

Sent via the Samsung Galaxy S9+, an AT&T 5G Evolution capable smartphone
Get Outlook for Android

From: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>
Sent: Wednesday, October 26, 2022 10:03:18 AM
To: Karen Peterson <karen@neurentmedical.com>
Cc: k222032@docs.fda.gov <k222032@docs.fda.gov>
Subject: K222032 510k Summary

Hi Karen,

We have some suggested edits for your 510k Summary. I think they are relatively minor – please see track changes in this document (given our time constraints I entered the edits myself).

Thanks,
Lindsay

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Ph: 240-402-1462
Email: lindsay.devries@fda.hhs.gov

U.S. Food and Drug Administration

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TECHNICAL REPORT

Number: (b)(4)

Revision:

Title: NEUROMARK (b)(4)

Written By: (b)(4)

Reviewed By

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NEURENTMedical

(b)(4)

Report NEUROMARK™ System

This document is uncontrolled when printed. Before use, check the Master Document List to verify that this is the current version

Document ID:	(b)(4)
Revision:	

Document Author:

Document Reviewers:

Document Approvals:

(b)(4)

Revision History:

(b)(4)

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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)*
K222032

Device Name
NEUROMARK® System

Indications for Use *(Describe)*
The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

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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NEURENTMedical

K222032

Special 510(k) Notification Cover Letter

July 8, 2022

FDA/CDRH/DCC
JUL 11 2022
RECEIVED

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) - WO66-G609#
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K212666, NEUROMARK® System, Date of Concurrence: 22 October 2021
Special 510(k) Notification – NEUROMARK® System

Dear Madam/Sir,

Neurent Medical hereby submits this **Special 510(k) Device Modification** to request a modification to our NEUROMARK® System.

The modification is to change the Device Treatment Tip (End Effector) material and base component to simplify (b)(4) We believe this modification is eligible for the **Special 510(k)** process since it has the same fundamental scientific technology and intended use as the predicate device.

In accordance with FDA Guidance 'eCopy Program for Medical Device Submissions', issued April 27, 2020, this cover letter along with an eCopy of the submission is provided.

General Information

Type of Submission	**Special 510(k)**
Basis for Submission	Device Modification
Submitter's name and Address	Neurent Medical, 1 Oran Point, Main Street, Oranmore, Co. Galway, H91 D7X2 Ireland
Contact Person	Karen E. Peterson Vice President Clinical, Regulatory and Quality (651) 398-4341 karen@neurentmedical.com
Establishment Registration	3016813690
Common Name	Radiofrequency Probe
Trade Name	NEUROMARK® System
Classification Regulation	21 CFR 878.4400
Classification Name	Electrical cutting and coagulation device and accessories
Classification Panel	General and Plastic Surgery
Class	Class II
Product Code	GEI
Identification of Predicate Device	NEUROMARK® System [K212666]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Device will be manufactured for Neurent Medical by (b)(4) (b)(4) The Device will be sterilized by (b)(4) (b)(4) The Console will be manufactured for Neurent Medical by (b)(4) (b)(4)

The following table outlines the principal factors in relation to design and use of the device.

Principal Factors of Design & Use	Yes	No
Is the device intended for prescription use (21 CFR 801 subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

There have been no prior submissions for these modifications to the NEUROMARK® System that is the subject of this pre-market notification.

Neurent Medical considers the information contained in this submission to be proprietary and not intended for public disclosure, except for the 510(k) Summary. Confidentiality is requested in accordance with 21 CFR 807.95.

Thank you for your consideration of our application. If you have any questions, please feel free to contact me by telephone at (651) 398-4341 or by email at karen@neurentmedical.com.

Sincerely,

(b)(6)

Karen E. Peterson
Vice President Clinical, Regulatory & Quality
Neurent Medical
karen@neurentmedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Karen,

Hope you are doing well. I have some interactive questions from the review team (please see below). If you could please send a response by Thursday September 15,

2022 by COB that would be great. Please let me know if that isn't doable.

Thanks,

Lindsay

Interactive Questions

(b)(4)

Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

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Hello Karen,

I have a requested modification to your 510(k) Summary. (b)(4)

(b)(4)

Please send me a modified 510(k) Summary by COB tomorrow, Friday October 21, 2022. If there is a time issue, please let me know.

Thanks,

Lindsay

Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

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Truthful and Accuracy Statement

[As Required by 21 CFR 807.87(l)]

I certify that, in my capacity as Vice President Clinical, Regulatory & Quality at Neurent Medical, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

July 8, 2022

Karen E Peterson **Date**

This is a new submission. 510(k) Number is unknown at the time of submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-2211; Released by CDRH on 09-09-2024

(b)(4)

Document Title:

(b)(4) NEUROMARK Verification Summary Report

Document Number:

(b)(4)

Revision:

(b)(4)

Release Date:

05 Jul 2022

For:

Neurent Medical
No.1 Oranpoint | Oranmore | Galway | Ireland | H91 D7X2

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Yes, that is fine if you concur. I will let you know if there is anything else. Thanks!

From: Karen Peterson <karen@neurentmedical.com>

Sent: Wednesday, October 26, 2022 12:28 PM

To: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>

Cc: k222032@docs.fda.gov

Subject: [EXTERNAL] Re: K222032 510k Summary

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Lindsay,

These look fine to me.

Let me know if this email response is all you need from me.

Thanks,

Karen

Sent via the Samsung Galaxy S9+, an AT&T 5G Evolution capable smartphone

Get Outlook for Android<https://aka.ms/AAb9ysg>

From: DeVries, Lindsay
<Lindsay.DeVries@fda.hhs.gov<mailto:Lindsay.DeVries@fda.hhs.gov>>

Sent: Wednesday, October 26, 2022 10:03:18 AM

To: Karen Peterson <karen@neurentmedical.com<mailto:karen@neurentmedical.com>>

Cc: k222032@docs.fda.gov<mailto:k222032@docs.fda.gov>
<k222032@docs.fda.gov<mailto:k222032@docs.fda.gov>>

Subject: K222032 510k Summary

Hi Karen,

We have some suggested edits for your 510k Summary. I think they are relatively minor - please see track changes in this document (given our time constraints I entered the edits myself).

Thanks,

Lindsay

Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

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Document Title:

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30 Jun 2022

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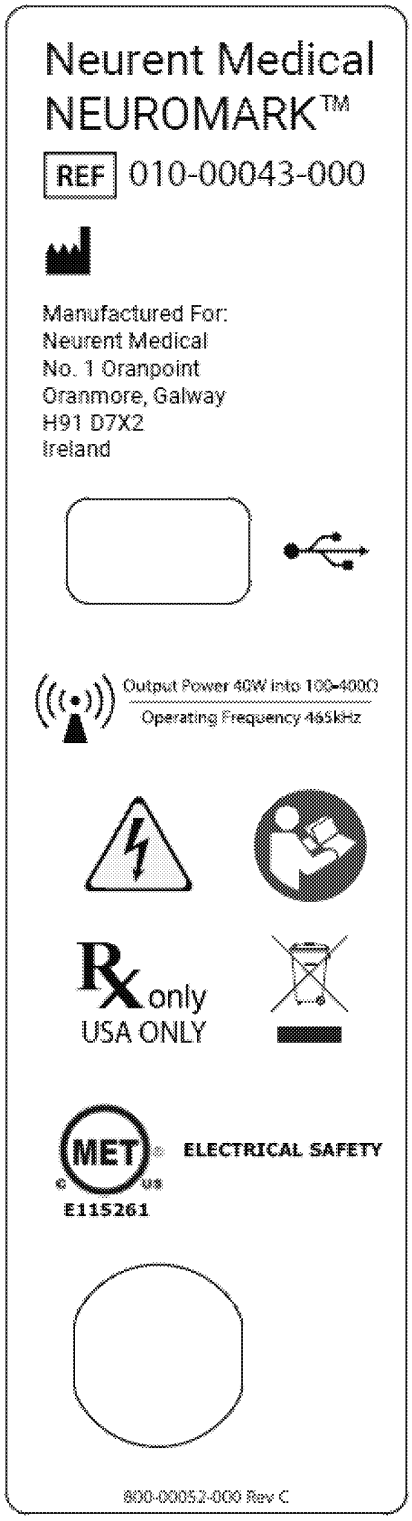
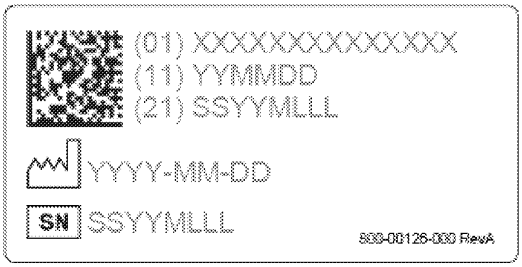
Attachment 10 – Predicate Console Current Packaging Label





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Hello Lindsay,

Thank you for sending the interactive questions. Attached is our response to the 3 questions. The following files are attached:

* Response to FDA Interactive Questions of 05Oct2022
* Attachment 1 Updated IFU redline
* Attachment 2 Updated IFU clean copy
* Attachment 3 Updated 510(k) Summary redline
* Attachment 4 Updated 510(k) Summary clean copy

Let me know if you need anything else.

Have a nice weekend,

Karen

From: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>

Sent: Wednesday, October 5, 2022 10:42 AM

To: Karen Peterson <karen@neurentmedical.com>

Cc: k222032@docs.fda.gov

Subject: K222032/S001: Interactive Questions

Hello Karen,

As you know, we are proceeding interactively with your submission for the Neuromark device modifications. I have three interactive questions for you (attached). If you could please provide responses to these questions by Monday, October 10, 2022 by COB that would be helpful. If you need more time, please let me know.

Thanks,

Lindsay

Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

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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)*
K222032

Device Name
NEUROMARK® System

Indications for Use *(Describe)*
The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

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)

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Hello Karen,

Hope you are doing well. I have some interactive questions from the review team (please see below). If you could please send a response by Thursday September 15,
2022 by COB that would be great. Please let me know if that isn't doable.

Thanks,
Lindsay

Interactive Questions

(b)(4)

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Ph: 240-402-1462
Email: lindsay.devries@fda.hhs.gov

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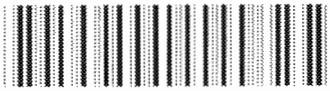

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TEST ARTICLE NAME AND IDENTIFICATION

(b)(4) NEUROMARK,
reference (b)(4) NEUROMARK,
batch: (b)(4)

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(b)(4)

SPONSOR

Neurent Medical
(b)(4)
No. 1 Oranpoint, Oranmore, Galway
H91 D7X2
Ireland

CONFIDENTIAL

STUDY TITLE

(b)(4)

TEST ARTICLE NAME AND IDENTIFICATION

(b)(4) NEUROMARK.
reference (b)(4) NEUROMARK.
batch: (b)(4)

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510(K) SUMMARY

(b)(4)

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Ms. Peterson,

I am the lead reviewer for K222032. I am writing to inform you that we have converted this file to a Traditional 510(k), for the reasons in the attached Special 510 (k) checklist. The new SI decision date is now September 9, 2022. Please let me know if you have any questions.

Thanks,
Lindsay

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology
Ear, Nose, and Throat Devices Team
CDRH/OPEQ/OHT1/DHT1B

Ph: 240-402-1462
Email: lindsay.devries@fda.hhs.gov

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Hello Lindsay,

Thank you for the requested modification to the 510(k) Summary. (b)(4)

(b)(4)

Attached is a redline copy and a clean copy of the updated 510(k) Summary.

Thanks much,
Karen

From: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>
Sent: Thursday, October 20, 2022 9:29 AM
To: Karen Peterson <karen@neurentmedical.com>
Cc: k222032@docs.fda.gov
Subject: K222032: 510k edits
Importance: High

Hello Karen,

I have a requested modification to your 510(k) Summary (b)(4)

(b)(4)

Please send me a modified 510(k) Summary by COB tomorrow, Friday October 21, 2022. If there is a time issue, please let me know.

Thanks,
Lindsay

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Phone: 240-402-1462
Email: lindsay.devries@fda.hhs.gov

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Hello Karen,

As you know, we are proceeding interactively with your submission for the Neuromark device modifications. I have three interactive questions for you (attached). If you could please provide responses to these questions by Monday, October 10, 2022 by COB that would be helpful. If you need more time, please let me know.

Thanks,

Lindsay

Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

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(b)(4)

Document Title:

NEUROMARK Generator System Report - DV Formal Test (b)(4)

Document Number:

(b)(4)

Revision:

(b)(4)

Release Date:

24 Jun 2022

For:

Neurent Medical
No.1 Oranpoint | Oranmore | Galway | Ireland | H91 D7X2

NOTICE OF PROPRIETARY AND CONFIDENTIAL PROPERTY

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October 26, 2022</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Lindsay DeVries.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hi Karen,

We have some suggested edits for your 510k Summary. I think they are relatively minor - please see track changes in this document (given our time constraints I entered the edits myself).

Thanks,

Lindsay

Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

[U.S. Food and Drug Administration]<http://www.fda.gov/>

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Final (b)(4) Report

(b)(4)

TEST FACILITY

(b)(4)

SPONSOR

Neurent Medical
(b)(4)
No. 1 Oranpoint, Oranmore, Galway
H91 D7X2
Ireland

CONFIDENTIAL

STUDY TITLE

(b)(4)

TEST ARTICLE NAME AND IDENTIFICATION

(b)(4) NEUROMARK,
reference (b)(4) NEUROMARK,
batch: (b)(4)

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(b)(4)

(b)(4) Protocol

TEST FACILITY

(b)(4)

SPONSOR

Neurent Medical
(b)(4)
No. 1 Oranpoint, Oranmore, Galway
H91 D7X2
Ireland

CONFIDENTIAL

STUDY TITLE

(b)(4)

TEST ARTICLE NAME AND IDENTIFICATION

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reference (b)(4) NEUROMARK,
batch (b)(4)

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NEURENTMedical

Special 510(k) Notification Cover Letter

July 8, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) - WO66-G609#
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K212666, NEUROMARK® System, Date of Concurrence: 22 October 2021
Special 510(k) Notification – NEUROMARK® System

Dear Madam/Sir,

Neurent Medical hereby submits this **Special 510(k) Device Modification** to request a modification to our NEUROMARK® System.

The modification is to change the Device Treatment Tip (End Effector) material and base component (b)(4) (b)(4). We believe this modification is eligible for the **Special 510(k)** process since it has the same fundamental scientific technology and intended use as the predicate device.

In accordance with FDA Guidance 'eCopy Program for Medical Device Submissions', issued April 27, 2020, this cover letter along with an eCopy of the submission is provided.

General Information

Type of Submission	**Special 510(k)**
Basis for Submission	Device Modification
Submitter's name and Address	Neurent Medical, 1 Oran Point, Main Street, Oranmore, Co. Galway, H91 D7X2 Ireland
Contact Person	Karen E. Peterson Vice President Clinical, Regulatory and Quality (651) 398-4341 karen@neurentmedical.com
Establishment Registration	3016813690
Common Name	Radiofrequency Probe
Trade Name	NEUROMARK® System
Classification Regulation	21 CFR 878.4400
Classification Name	Electrical cutting and coagulation device and accessories
Classification Panel	General and Plastic Surgery
Class	Class II
Product Code	GEI
Identification of Predicate Device	NEUROMARK® System [K212666]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The Device will be manufactured for Neurent Medical by (b)(4). The Device will be sterilized by (b)(4). The Console will be manufactured for Neurent Medical by (b)(4).

The following table outlines the principal factors in relation to design and use of the device.

Principal Factors of Design & Use	Yes	No
Is the device intended for prescription use (21 CFR 801 subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

There have been no prior submissions for these modifications to the NEUROMARK® System that is the subject of this pre-market notification.

Neurent Medical considers the information contained in this submission to be proprietary and not intended for public disclosure, except for the 510(k) Summary. Confidentiality is requested in accordance with 21 CFR 807.95.

Thank you for your consideration of our application. If you have any questions, please feel free to contact me by telephone at (651) 398-4341 or by email at karen@neurentmedical.com.

Sincerely,

(b)(6)

Karen E. Peterson
Vice President Clinical, Regulatory & Quality
Neurent Medical
karen@neurentmedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NEUROMARK™ (b)(4)

(b)(4) Report

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05 Jul 2022

For:

Neurent Medical
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Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2022. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

Neurent Medical Limited
No. 1 Oran Point
Main Street
Oranmore
Galway

IE

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Kenny Walsh

2.1 E-MAIL ADDRESS
kenny@neurentmedical.com

2.2 TELEPHONE NUMBER (include Area code)
87-9471202

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice
[ ] De Novo Request

3.1 Select a center

[X] CDRH
[ ] CBER

3.2 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required [ ] NO, I am not a small business

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qualifying documents to FDA

4.1 If Yes, please enter your Small Business Decision Number: (b)(4)

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)

[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

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8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

26-May-2022

Form FDA 3601 (08/19)

"Close Window" Print Cover sheet

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Ms. Peterson,

I am the lead reviewer for K222032. I am writing to inform you that we have converted this file to a Traditional 510(k), for the reasons in the attached Special 510(k) checklist. The new SI decision date is now September 9, 2022. Please let me know if you have any questions.

Thanks,

Lindsay

Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

CDRH/OPEQ/OHT1/DHT1B

Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/r/cdrhcustomerservice?ID=1323&S=E

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 7/29/2022 7:29:29 PM
To: karen@neurentmedical.com
CC: DCCLetters@fda.hhs.gov
Subject: K222032/S001 Acknowledgement Letter
Attachments: K222032-S001-Acknowlegement Letter.pdf

July 29, 2022

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

*** This is a system-generated email notification ***

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Acknowlegement Letter

07/29/2022

Karen E. Peterson, Vice President Clinical, Regulatory & Quality
Neurent Medical
1 Oran Point, Main Street, Oranmore
Galway,
Connaught H91D7X2 IRELAND

Dear Karen E. Peterson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov .

Submision Number: K222032/S001
Received: 07/29/2022
Applicant: Neurent Medical
Device: NEUROMARK System

We will notify you when the review of this submission document has been completed or if any additional information is required.If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm .

Sincerely yours,

Center for Devices and Radiological Health

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTI/DHTIB
WO66 RM1257
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-1462

Premarket Notification 510(k) Review

Date: October 26, 2022

Reviewer: Lindsay DeVries

510(k)# K222032/S001 Subject: Traditional

Applicant: Neurent Medical	**Device Trade Name:** NEUROMARK System
Contact Name: Karen Peterson	**Contact Title:** Vice President Clinical, Regulatory & Quality
Correspondent Firm: Neurent Medical	**Phone:** (651) 398-4341 **Email:** karen@neurentmedical.com
Received Date: July 29, 2022	**Due Date:** October 27, 2022
Pro Code(s): GEI **Class:** II **Reg #:** 878.4400	**Reg Name:** Electrosurgical Cutting And Coagulation Device And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K212666	GEI, GXD	Neuromark System	Neurent Medical

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NEURENTMedical

NEUROMARK

Neurent Medical Ltd.
1 Oran Point, Main Street,
Oranmore, Co. Galway, Ireland
Phone: +353 91 416812
Email: productfeedback@neurentmedical.com
Website: www.neurentmedical.com

Rx Only

INSTRUCTIONS FOR USE – NEUROMARK® SYSTEM
MAX VOLTAGE: 130 VRMS

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(b)(4)

Document Title:

NEUROMARK Generator System (b)(4)

(b)(4)

Document Number:

(b)(4)

Revision:

(b)(4)

Release Date:

11 May 2022

For:

Neurent Medical
No.1 Oranpoint | Oranmore | Galway | Ireland | H91 D7X2

NOTICE OF PROPRIETARY AND CONFIDENTIAL PROPERTY

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Hi Lindsay,

These look fine to me.

Let me know if this email response is all you need from me.

Thanks,

Karen

Sent via the Samsung Galaxy S9+, an AT&T 5G Evolution capable smartphone

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From: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>

Sent: Wednesday, October 26, 2022 10:03:18 AM

To: Karen Peterson <karen@neurentmedical.com>

Cc: k222032@docs.fda.gov <k222032@docs.fda.gov>

Subject: K222032 510k Summary

Hi Karen,

We have some suggested edits for your 510k Summary. I think they are relatively minor - please see track changes in this document (given our time constraints I entered the edits myself).

Thanks,

Lindsay

Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

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Hello Lindsay,

I am doing well – hope all is well with you too. Thanks for sending the interactive questions. Attached is our response to your 3 questions.

Let me know if you need anything else.

Have a good day,

Karen Peterson
VP Clinical, Regulatory and Quality
Neurent Medical
Cell: 651-398-4341

From: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>
Sent: Tuesday, September 13, 2022 3:10 PM
To: Karen Peterson <karen@neurentmedical.com>
Cc: k222032@docs.fda.gov
Subject: K222032 interactive questions
Importance: High

Hello Karen,

Hope you are doing well. I have some interactive questions from the review team (please see below). If you could please send a response by Thursday September 15,
2022 by COB that would be great. Please let me know if that isn't doable.

Thanks,
Lindsay

Interactive Questions

(b)(4)

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Ph: 240-402-1462
Email: lindsay.devries@fda.hhs.gov

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Declaration of Conformity with Design Controls

[As Required by 21 CFR 820.30]

I certify that, in my capacity as Director of Quality & Regulatory at Neurent Medical, that:

- As required by the risk analysis, all design verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met;
- Neurent Medical complies with and is not currently in violation of the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review, upon request.

(b)(6)

July 08, 2022

Kenny Walsh — Date

This is a new submission. 510(k) number is unknown at the time of submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Have a good day,

Karen Peterson

VP Clinical, Regulatory and Quality

Neurent Medical

Cell: 651-398-4341

From: DeVries, Lindsay <Lindsay.DeVries@fda.hhs.gov>

Sent: Tuesday, September 13, 2022 3:10 PM

To: Karen Peterson <karen@neurentmedical.com>

Cc: k222032@docs.fda.gov

Subject: K222032 interactive questions

Importance: High

Hello Karen,

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Thanks,

Lindsay

Interactive Questions

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Lindsay DeVries, Au.D., Ph.D.

Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Ph: 240-402-1462

Email: lindsay.devries@fda.hhs.gov<mailto:lindsay.devries@fda.hhs.gov>

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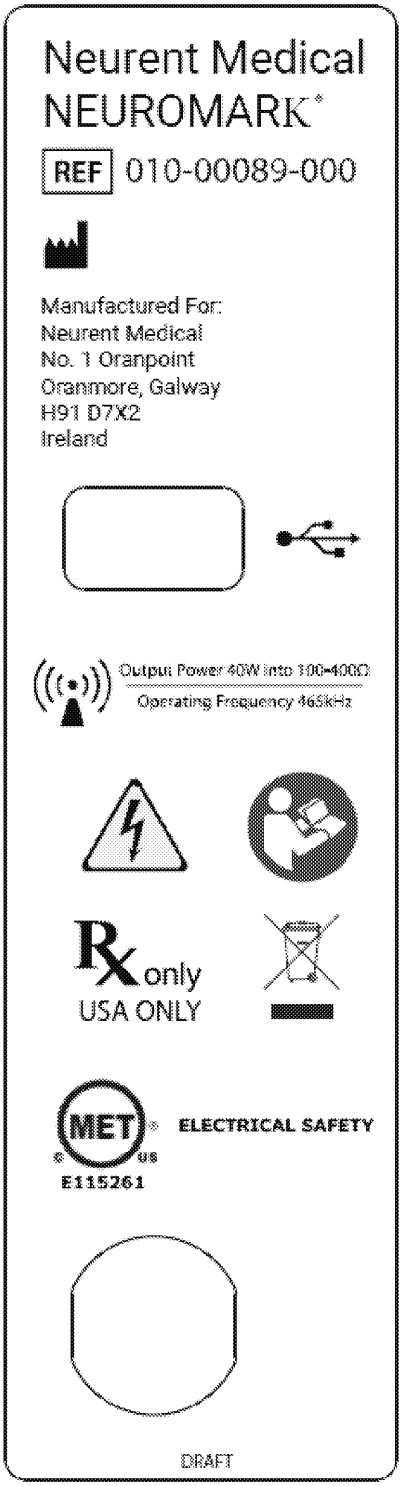

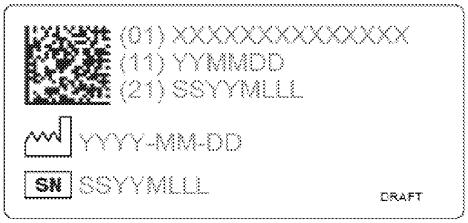

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Final (b)(4) Report

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reference (b)(4) NEUROMARK,
batch (b)(4)

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(b)(4)

(b)(4) Protocol

TEST FACILITY

(b)(4)

SPONSOR

Neurent Medical
(b)(4)
No. 1 Oranpoint, Oranmore, Galway
H91 D7X2
Ireland

STUDY TITLE

(b)(4)

TEST ARTICLE NAME AND IDENTIFICATION

(b)(4) NEUROMARK,
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July 26, 2022</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K222032. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K222032, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 01/22/2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Lindsay DeVries. The file is being reviewed in Office of Health Technology 1, Division of Health Technology 1 B. The first line supervisor is the Assistant Director, ENT Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

For additional information about the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

 *** This is a system-generated email notification ***

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Final (b)(4) Report

(b)(4)

TEST FACILITY

(b)(4)

SPONSOR

Neurent Medical
(b)(4)
No. 1 Oranpoint, Oranmore, Galway
H91 D7X2
Ireland

CONFIDENTIAL

STUDY TITLE

(b)(4)

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(b)(4) Protocol

TEST FACILITY

(b)(4)

SPONSOR

Neurent Medical
(b)(4)
No. 1 Oranpoint, Oranmore, Galway
H91 D7X2
Ireland

STUDY TITLE

(b)(4)

TEST ARTICLE NAME AND IDENTIFICATION

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K222032 S001 NEUROMARK® System

Modification to the NEUROMARK® Device Treatment Tip (End Effector)

Response to FDA 510(k) Acceptance Checklist for a Traditional 510(k) dated July 26, 2022

Please find below the FDA requests from the identified sections of the 510(k) Acceptance Checklist for a Traditional 510(k) dated July 26, 2022, followed by Neurent Medical's responses.

(b)(4)

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(b)(4)

Document Title:

NEUROMARK (b)(4) Report

(b)(4)

Document Number:

(b)(4)

Revision:

(b)(4)

Release Date:

05 Jul 2022

For:

Neurent Medical
No.1 Oranpoint | Oranmore | Galway | Ireland | H91 D7X2

NOTICE OF PROPRIETARY AND CONFIDENTIAL PROPERTY

(b)(4)

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTI/DHTIB
WO66 RM1257
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-1462

Premarket Notification 510(k) Review

Date: October 26, 2022

Reviewer: Lindsay DeVries

510(k)# K222032/S001 Subject: Traditional

Applicant: Neurent Medical	**Device Trade Name:** NEUROMARK System
Contact Name: Karen Peterson	**Contact Title:** Vice President Clinical, Regulatory & Quality
Correspondent Firm: Neurent Medical	**Phone:** (651) 398-4341 **Email:** karen@neurentmedical.com
Received Date: July 29, 2022	**Due Date:** October 27, 2022
Pro Code(s): GEI **Class:** II **Reg #:** 878.4400	**Reg Name:** Electrosurgical Cutting And Coagulation Device And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K212666	GEI, GXD	Neuromark System	Neurent Medical

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Digital Signature Concurrence Table (Doc ID: 04500.14.06)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
Reviewer Sign-Off	Lindsay A. Devries -S Digitally signed by Lindsay A. Devries -S Date: 2022.10.26 12:44:31 -04'00'

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Document Title:

NEUROMARK (b)(4)

(b)(4) Document

Document Number:

(b)(4)

Revision:

(b)(4)

Release Date:

11 May 2022

For:

Neurent Medical
No.1 Oranpoint | Oranmore | Galway | Ireland | H91 D7X2

NOTICE OF PROPRIETARY AND CONFIDENTIAL PROPERTY

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NEUROMARK

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Oranmore, Co. Galway, Ireland
Phone: +353 91 416812
Email: productfeedback@neurentmedical.com
Website: www.neurentmedical.com

Rx Only

INSTRUCTIONS FOR USE – NEUROMARK® SYSTEM
MAX VOLTAGE: 130 VRMS

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NEURENTMedical

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Rx Only

INSTRUCTIONS FOR USE – NEUROMARK® SYSTEM
MAX VOLTAGE: 130 VRMS

DEVICE DESCRIPTION

The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis.

The NEUROMARK® System is composed of:

1. The NEUROMARK® Device and
2. The NEUROMARK® Radiofrequency (RF) Console

NEUROMARK® Device

The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft and treatment tip. The treatment tip, which is referred to as the *end effector*, consists of an array of bipolar electrodes that deliver bipolar RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery. The shaft of the device is pre-shaped to aid access and delivery to the nasal cavity but is malleable to allow the user to bend or shape it to accommodate variations in anatomy to access the desired treatment area. The NEUROMARK® Device is operated via handle, slider and activation button. Once in the desired position within the nasal cavity, the operator moves the slider backwards which retracts the outer sheath, deploying the *end effector*. Using the activation button, the user initiates a bio-impedance check to assess and confirm contact between the *end effector* and the treatment area. Once the System confirms contact has been achieved, a subsequent press of the activation button initiates the RF energy delivery cycle.

The NEUROMARK® Device is intended for single use and provided sterile (EO).

The NEUROMARK® Device (Figure 1) is designed for use with the NEUROMARK® Radiofrequency (RF) Console; it includes features to allow compatibility and authentication once connected, via a flexible cable, to the Console.

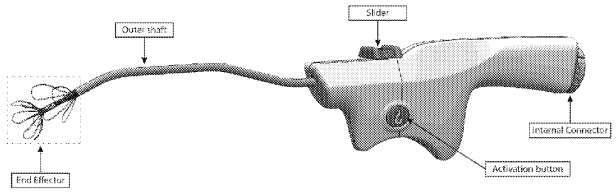

Figure 1: NEUROMARK® Device

NEUROMARK® Radiofrequency (RF) Console

The NEUROMARK® Console delivers, monitors and controls RF energy to the Device.

The Console is mounted on an ergonomic mobile stand for ease of use. The Console includes a Graphical User Interface (GUI) which provides operational instructions for the procedure, directs the user to select nasal cavities for treatment, indicates when the device is in contact with tissue and ready to start treatment, provides status of therapy and indicates when the procedure is complete. The NEUROMARK™ Console works in conjunction with software.

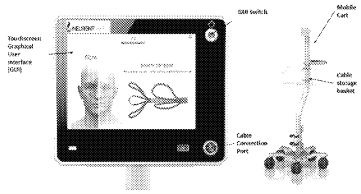

Figure 2: RF Console/Graphical User Interface

INDICATIONS FOR USE

The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

CONTRAINDICATIONS

- None.

WARNINGS

System Warnings

- It is important that the NEUROMARK® System operator be familiar with the system User's Guide, its precautions, procedures and safety issues.
- Do not use the NEUROMARK® System in the presence of flammable anaesthetics. Avoid potential ignition or explosion of gases.
- Disconnect power to the NEUROMARK® System when not in use.
- Disconnect power to the NEUROMARK® System before cleaning the unit to avoid electrical macro shock.
- Do not attach unapproved components to the NEUROMARK® System to avoid electrical macro shock.
- To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the NEUROMARK® System to hospital grade receptacles only.
- The NEUROMARK® Radiofrequency Console adheres with EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered, and the user should take whatever steps are necessary to eliminate or reduce the source of the interference. Diminished performance may lengthen operating time for anesthetized patient.
- Medical Electrical Equipment needs special Precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Guide.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NEUROAMRK™ System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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- The NEUROMARK® System has not been tested for known sources of electromagnetic interference such as Magnetic Resonance Imaging (MRI), Computerized Tomography (CT), diathermy and electromagnetic security systems such as metal detectors, and should not be used in conjunction with or in proximity to such technology. Use of accessories and cables other than those specified by Neurent Medical may result in decreased performance of the NEUROMARK® System.
- The NEUROMARK® System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the NEUROMARK® System should be observed to verify normal operation in the configuration in which it will be used.
- Do not service, repair and/or modify the NEUROMARK® System. Where appropriate contact Neurent Medical.

Device & Component Warnings

- Do not use any parts other than Neurent Medical NEUROMARK® System components as damage or substandard performance could result.
- Always inspect the components before, during and after use for any damage. If damage is observed, do not use damaged part. Always replace damaged parts.
- Employ endoscopic visualisation, when using the NEUROMARK® Device.
- Discontinue powered application in the event of lack of visualization of surgical site.
- Electrical contacts must be dry prior to use.
- Do not attempt to remove or change NEUROMARK® Device, while the therapy is active.
- Do not immerse the system components, except as noted.
- A system that is not functioning properly should not be used.
- Make sure that the cable attachment is in the locked position prior to therapy application, as an incorrect connection may result in the attachment accidentally being unlocked.
- Smoke and/or excessive heat may be generated if cable attachment is not in the fully locked position. This may result in thermal injury to the surgeon or staff.
- The NEUROMARK® Device will not run properly unless the attachment is in the locked position.
- DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause fire.
- DO NOT place the NEUROMARK® Device or cables on the patient or in an unsecured location during surgery.
- DO NOT perform overlapping lesions on target tissue site.

PROCEDURE

Precautions

- Do not conduct treatments without carefully reading the Instructions before use of this device; this will help to reduce the potential risks and complications associated with the trans-nasal technique.
- Do not alter this device in any way other than detailed within the operational instructions below.
- Only those clinicians who are trained in trans-nasal procedures and catheter delivery systems should use this device.
- Do not reuse this device. Thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from reuse of this device.
- Store in a cool, dark, dry place.
- Do not use this device if there is any evidence of damage caused during the shipment of the device.

Procedural Considerations

Carefully reading the Instructions before use of this device will help to reduce the potential dangers associated with the trans-nasal technique such as trauma of the nasal mucosa.
Only those clinicians who are specially trained in trans-nasal procedures should use this device. Visual endoscopic guidance should be used to confirm positioning throughout the procedure. Trans-nasal procedures should be performed only in facilities appropriately equipped and staffed to perform such procedures.

Operational Instructions

NOTE: Typical variations may occur within these steps, depending on available capabilities and operator preference. These will be listed as "OPT", and details discussed.

DEFINITION OF SYMBOLS USED

LOT	Lot Number/Batch Code
REF	Catalogue Number
	Date of Manufacture
	Expiry Date
	Manufacturer
STERILE EO	Sterilized using ethylene oxide
	Do not re-use
	Do not re-sterilize
	Do not use if packaging is damaged
	Consult instructions for use
	Consult the instructions for use for cautionary information
QTY: 1 EA	Quantity
Rx Only	Federal (USA) law restricts this device to sale by or on order of a physician

POTENTIAL HAZARDS/ADVERSE EVENTS.

Potential adverse effects related to the use of radiofrequency energy on tissue in the nasal airway include infection, bleeding (mild or severe), mucosal trauma, mucosal perforation, superficial burns, temporary pain/discomfort, temporary headache, scar formation with increased obstruction, cosmetic deformity, sensory (olfactory) changes at treatment site, septal perforation, worsened eustachian tube function, atrophic rhinitis or dry nose.

NEUROMARK® DEVICE PREPARATION

1. Retrieve NEUROMARK® Device package from storage
   - ***Caution:*** Check the expiry date on the label. DO NOT use product that is past its expiry date. The manufacturer cannot assure performance of the product after its expiry date.
2. Open the box and remove the pouch from the shelf carton.
   - ***Caution:*** Inspect the pouch for any damage. DO NOT use product where the pouch is damaged or breached in any way. Sterilization may be compromised.
   - ***Caution:*** Check the expiry date on the pouch label. DO NOT use product that is past its expiry date. The manufacturer cannot assure performance of the product after its expiry date.
   - ***Caution:*** Users of this device should follow the steps outlined in this IFU for effective therapy.
3. Open the pouch at the chevron seal and remove the tray from the pouch.
   - ***Caution:*** Inspect the device in the tray for any damage. DO NOT use product where the product appears damaged.
4. Connect the device connector to the console connection cable.

LOCAL ANESTHETIC DELIVERY

- Obtain nasal cavity access and inspect anterior region for local anesthetic delivery
- Under endoscopic guidance, access the lateral mucosal wall target site

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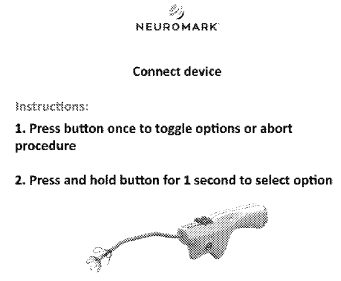
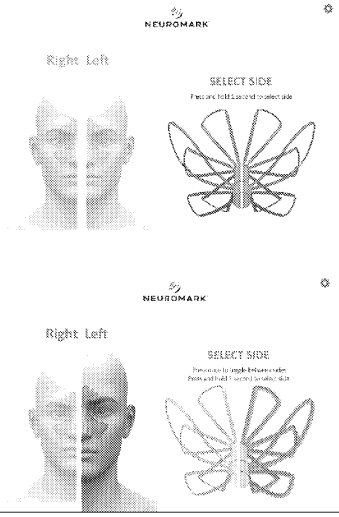
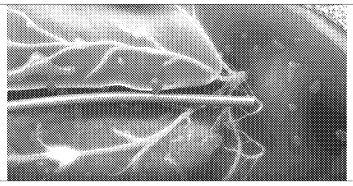
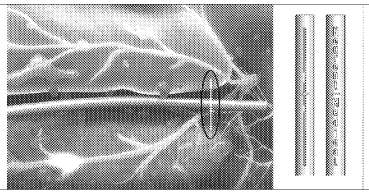
- Administer local anesthetic per hospital procedures and within targeted dosage range of those procedures
- Confirm the effectiveness of the local anesthesia throughout the lateral wall of the nasal cavity through to posterior recess of nasal cavity
- Dispose of the patient contacting and single use local anesthesia materials in accordance with hospital procedures

NEUROMARK® PROCEDURE

	Use Step	Visual Examples
1.	Ensure that the console has been setup in accordance with the instructions for use provided with the console (IFU-005)	
2.	Remove the device from the tray in accordance with the instructions for use and using the guide marks on the tray	
3.	Connect a valid NEUROMARK® device to the console long cable. • ***NOTE**: If an invalid or expired* NEUROMARK® device is connected to the console, the user will be not be able to proceed past the "Connect device" screen to the main treatment screen until a valid device is connected.	
4.	On the console GUI screen, select the patient's nasal cavity to be treated. The selected nasal cavity side will be highlighted on the GUI display.	
5.	Insert the device into the selected nares under endoscopic guidance • ***Caution**: DO NOT use product where the product appears damaged.*	
6.	Advance the device to the posterior recesses of the inferior/middle/superior meatus under endoscopic guidance *(OPTIONAL – If required, carefully manipulate the shaft configuration to reduce / exaggerate the shaft curvature to enhance delivery – see figure 3)*	
7.	Rotate/re-orientate the NEUROMARK® Device so that the visual shaft marking denoting "Neurent Medical" is facing upwards. *This facilitates ease of positioning and indicates the correct deployment orientation of the end effector which targets the superior and inferior posterior nerves or their branches underlying the mucosa.*	
8.	Under endoscopic guidance, align the inter stage marker on the shaft to the lateral attachment of the middle turbinate. *This provides an approximation of the gap between the distal and proximal end effector leaflets to aid positioning.*	
9.	Move the slider backwards to deploy the end effector fully • ***CAUTION**: Ensure that the slider is fully pulled back to allow for full deployment of the end effector*	
10.	Make any necessary minor adjustments to ensure that the device is positioned in the correct anatomical position. Verify the correct position endoscopically. • ***CAUTION**: Ensure that the proximal end of the end effector wraps around the middle turbinate anterior to the attachment of the turbinate to the lateral wall.* • ***NOTE**: The end effector consists of a distal and proximal stage. The leaflets are super elastic and spring out to enforce mucosal apposition on the lateral wall. The multi-stage elastic leaflet set-up accommodates the area of the posterior nasal nerves.*	

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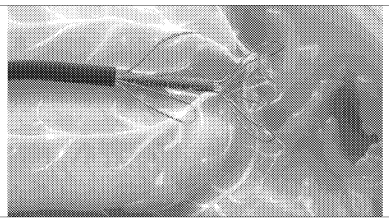
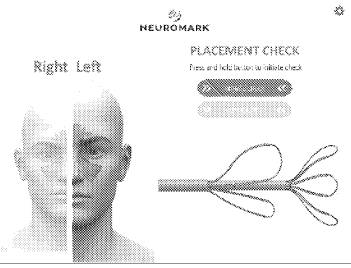
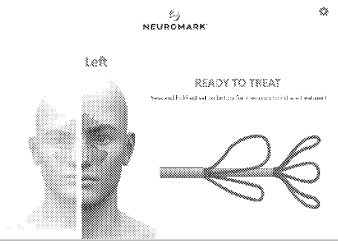


11. Once fully deployed and positioned appropriately, press the device activation button to begin baseline bioelectric evaluation to confirm electrode apposition.

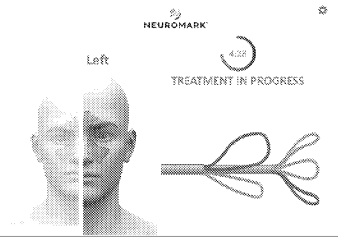


12. Observe the apposition status of the device on the GUI and make any minor adjustments to gain optimal apposition.
Blue indicates that the leaflet is in contact with the nasal tissue.

13. When GUI indicates "ready to treat", press the device activation button for a 2 second hold. This begins the therapy.



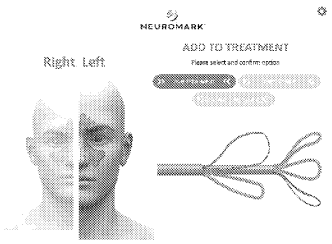
14. Hold the device in place while treatment is in progress and wait for further message from GUI.

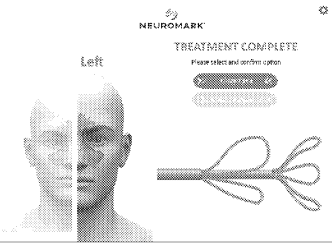


15. When the treatment cycle is completed the GUI screen will highlight in green the leaflets that have completed treatment.

Any leaflets that were not contacting the tissue during the first placement check and were not active in the treatment cycle will be made available to attempt to complete a treatment with these leaflets. To attempt positioning with these leaflets, select "Add Treatment" and, under endoscopic guidance, attempt micro-adjustments to gain non-overlapping apposition with these leaflets.
CAUTION: Avoid large movements of the end effector when trying to Add Treatment as this may result in overlapping lesions. Under endoscopic guidance, make micro-movements to attempt to gain apposition and ensure that lesions do not overlap. If these are not successful do not make large position movements of the end effector.
Return to Step 10.

Note: This option will not be available if all leaflets completed the treatment cycle.

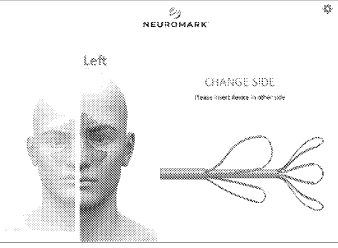




16. To treat the other nasal cavity, select "Change Side"

Remove the device from the nasal cavity, constrain the end effector by moving the slider forward and introduce the device into the second nasal cavity.

Return to Step 10



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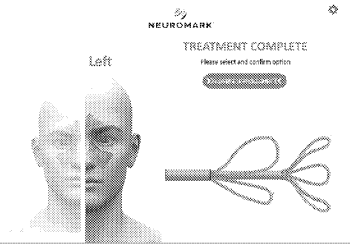
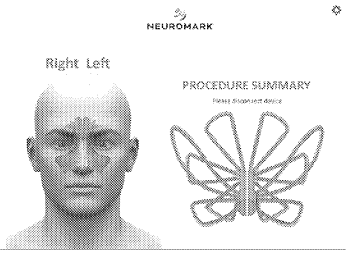
17. When the treatment is complete select "Complete Procedure"



18. A procedure summary is presented for review highlighting in green all leaflets that were activated in the treatment cycle.



19. EMERGENCY STOP: A single press of the device button or a single press of the backup RF ON/OFF switch on the console will stop delivery of RF energy during the treatment cycle.

EMC SPECIFICATIONS

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The NEUROMARK® System is intended for use in the electromagnetic environment specified below. The customer or the user of the NEUROMARK® System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The NEUROMARK® System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The NEUROMARK® System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class D	
Voltage fluctuations/flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Essential performance was shown to be maintained for all levels of electromagnetic immunity testing. Essential performance for this system includes accurate measurement of RF power levels.
A degradation in essential performance will generally always be prevented by an alert or error associated with that function. In the unlikely event that an alert or error does not prevent degradation of essential performance by an electromagnetic disturbance, one or more aspects of essential performance, as defined above, may be impacted.

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines Both at 100kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/output lines Both at 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	For power supply lines: ±0.5kV and ±1kV line(s) to line(s) ±0.5kV, ±1kV, and ±2kV line(s) to ground For signal input/output ports: ±2kV line(s) to ground	For power supply lines: ±0.5kV and ±1kV line(s) to line(s) ±0.5kV, ±1kV, and ±2kV line(s) to ground For signal input/output ports: ±2kV line(s) to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles 0% UT for 250/300 cycles	0% UT for 0.5 cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles 0% UT for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Console requires continued operation during power mains interruptions, it is recommended that the Console be powered from an uninterruptible power supply.
Note: UT is the AC mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V ISM bands between 0.15 MHZ and 80 MHZ 80% AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V ISM bands between 0.15 MHZ and 80 MHZ 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz Specific communication frequencies tested per table 6	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz Specific communication frequencies tested per table 6	Recommended separation distance: d = [1.17] √P d = [1.17] √P 80 MHz to 800 MHz P = [2.33] √P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: at 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

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The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones, and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System including cables or any of its components are used exceeds the applicable RF compliance level above, the System including cables should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System including cables. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Guidance and Manufacturer's Declaration – Enclosure port immunity levels to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	GM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800;CDMA 1900;GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Recommended separation distances between portable and mobile RF communications equipment and the Console including cables.

The Console (including cables) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Console (including cables) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Console including cables as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter (m)**		
	150kHz to 80MHz **d = [1.17] √P**	**80kHz to 800MHz** **d = [1.17] √P**	**800kHz to 2.5GHz** **d = [2.33] √P**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: at 80MHz and 800MHz, the separation distance for the higher frequency range applies. Note 2: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Recommended areas and limits for re-shaping the shaft, if required, to suit anatomy. Do not shape the shaft outside of the areas shown or in excess of the recommended shape range. Shape the device with small careful movements taking care not to damage the shaft.

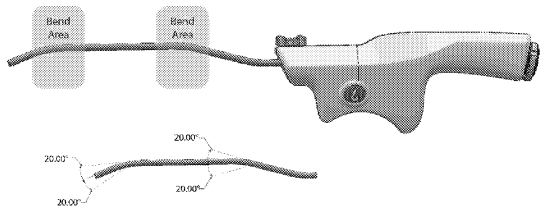

Figure 3: Shaft Shaping Diagram

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NEURENTMedical

July 28, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) - WO66-G609#
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K222032 S001 NEUROMARK® System
Response to FDA Acceptance Checklists of July 18, 2022 and July 26, 2022

Dear Madam/Sir,

This Supplement to the above 510(k) Premarket Notification responds to the FDA requests in the 510(k) Acceptance Checklists of July 18, 2022, and July 26, 2022. We believe the enclosed response addresses all the requests identified by FDA.

In accordance with FDA Guidance 'eCopy Program for Medical Device Submissions', issued April 27, 2020, this cover letter along with an eCopy of the submission is provided.

Neurent Medical considers the information contained in this submission to be proprietary and not intended for public disclosure, except for the 510(k) Summary. Confidentiality is requested in accordance with 21 CFR 807.95.

Thank you for your consideration of the information provided in this submission. If you have any questions, please feel free to contact me by telephone at (651) 398-4341 or by email at karen@neurentmedical.com.

Sincerely,

(b)(6)

Karen E. Peterson
Vice President Clinical, Regulatory & Quality
Neurent Medical
karen@neurentmedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 7/11/2022 6:48:34 PM
To: karen@neurentmedical.com
CC: DCCLetters@fda.hhs.gov
Subject: K222032 Acknowledgement Letter
Attachments: K222032-Acknowlegement Letter.pdf

July 11, 2022

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

*** This is a system-generated email notification ***

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U.S. FOOD & DRUG ADMINISTRATION

Acknowlegement Letter

07/11/2022

Karen E. Peterson, Vice President Clinical, Regulatory & Quality
Neurent Medical
1 Oran Point, Main Street, Oranmore
Galway,
Connaught H91D7X2 IRELAND

Dear Karen E. Peterson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov .

Submision Number: K222032
Received: 07/11/2022
Applicant: Neurent Medical
Device: NEUROMARK System

We will notify you when the review of this submission document has been completed or if any additional information is required.If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm .

Sincerely yours,

Center for Devices and Radiological Health

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(b)(4)

Document Title:

NEUROMARK Trace Report

Document Number:

(b)(4)

Revision:

(b)(4)

Release Date:

11 July 2022

For:

Neurent Medical
No.1 Oranpoint | Oranmore | Galway | Ireland | H91 D7X2

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September 27, 2022</br></br>

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K222032/S001 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

 *** This is a system-generated email notification ***

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Special 510(k) – Device Modification

NEUROMARK® System

Modification to the NEUROMARK® Device Treatment Tip (End Effector)

July 8, 2022

Submitted by:

Karen E Peterson
Vice President Clinical, Regulatory & Quality
Neurent Medical
1 Oran Point, Main Street, Oranmore, Co. Galway, H91 D7X2,
Ireland

Neurent Medical considers all information within this Special 510(k) notification pertaining to the design of the device and testing to be confidential. Neurent Medical requests that the information herein be protected as such.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table of Contents

1. Medical Device User Fee Cover Sheet (Form FDA 3601) 4
2. CDRH Premarket Review Submission Cover Sheet (Form FDA 3514) 5
3. 510(k) Cover Letter 6
4. Refuse to Accept Checklist 7
5. Indications for Use Statement (Form FDA 3881) 8
6. 510(k) Summary 9
7. Truthful and Accuracy Statement 11
8. Class III Summary and Certification 12
9. Financial Disclosure / Certification 13
10. General Use of Standards 14
11. Device Description and Comparison 15
    11.1 Device Description 15
    11.2 Comparison to Cleared Device 15
    11.3 Changes Made Since the Last Submission 18
    11.4 Intended Use 19
    11.5 Proposed Labeling 19
12. Substantial Equivalence Discussion 20
13. Risk Analysis and Verification / Validation Activities 22
    13.1 Risk Analysis Methods & Results 22
    13.2 Device Specifications 24
    13.3 Declaration of Conformity 24
    13.4 Summary of Verification / Validation Activities 24
        13.4.1 Design Verification (DV) Testing 25
        13.4.2 (b)(4) Testing 28
14. Sterilization (b)(4) 30
15. Biocompatibility Testing 32
16. Console Software Testing 34
17. Electrical & Thermal Safety Testing 39

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-2211; Released by CDRH on 09-09-2024

List of Figures

Figure 1: Proposed Modification 16

List of Tables

Table 1: Proposed Modification to Device 17
Table 2: Changes Made Since Last Submission 18
Table 3: Comparison of Subject Device to Previously Cleared, Predicate Device 20
Table 4: Risks Associated with Modifications by Mitigation Activity 22
Table 5: Design Verification Testing 25
Table 6: (b)(4) Summary Results 29
Table 7: (b)(4) Summary Results 31
Table 8: Biocompatibility Summary Results 32
Table 9: Software Requirements Changes Summary 35
Table 10: Summary of Software Testing Relating to Software Requirements Changes 37
Table 11: Electrical Safety Summary Results 39
Table 12: Thermal Safety Summary Results 41

List of Attachments

Attachment 01 Medical Device User Fee Cover Sheet (Form FDA 3601)
Attachment 02 CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)
Attachment 03 510(k) Cover Letter
Attachment 04 Special 510(k) Refuse to Accept Checklist
Attachment 05 Indications for Use Statement (Form FDA 3881)
Attachment 06 Truthful and Accuracy Statement
Attachment 07 Subject Device Packaging Label
Attachment 08 Predicate Device Current Packaging Label
Attachment 09 Subject Console Packaging Label
Attachment 10 Predicate Console Current Packaging Label
Attachment 11 Device Instructions For Use (IFU) Red Line Copy
Attachment 12 Device Instructions For Use (IFU) Clean Copy
Attachment 13 Console Instructions For Use (IFU)
Attachment 14 Declaration of Conformity with Design Controls

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

The Medical Device User Fee Cover Sheet is in Attachment 01.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET (FORM FDA 3514)

The CDRH Premarket Review Submission Cover Sheet is in Attachment 02.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. 510(K) COVER LETTER

The 510(k) Cover Letter is in Attachment 03.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. REFUSE TO ACCEPT CHECKLIST

The Special 510(k) Refuse to Accept Checklist is in Attachment 04.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5. INDICATIONS FOR USE STATEMENT (FORM FDA 3881)

The Indications for Use Statement is in Attachment 05.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6. 510(K) SUMMARY

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7. TRUTHFUL AND ACCURACY STATEMENT

The Truthful and Accuracy Statement is in Attachment 06.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8. CLASS III SUMMARY AND CERTIFICATION

Not applicable, the NEUROMARK® System is a class II device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9. FINANCIAL DISCLOSURE / CERTIFICATION

Not applicable, no clinical data is submitted with this application.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10. General Use of Standards

Refer to Attachment 02 CDRH Premarket Review Submission Cover Sheet (Form FDA 3514) for a listing of standards used in this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11. DEVICE DESCRIPTION AND COMPARISON

11.1 Device Description

The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis.

The NEUROMARK® System is composed of the NEUROMARK® Device and the NEUROMARK® Radiofrequency (RF) Console.

The NEUROMARK® Device is a hand-held, single-use, bipolar radiofrequency device which comprises a handle, shaft, and treatment tip. The treatment tip, which is referred to as the End Effector, consists of an array of bipolar electrodes that deliver RF energy while monitoring feedback on tissue bio-impedance changes allowing for controlled RF energy delivery. The shaft of the device is pre-shaped to aid access and delivery to the nasal cavity but is malleable to allow the user to bend or shape it to accommodate variations in anatomy to access the desired treatment area. The NEUROMARK® Device is operated via handle, slider and activation button. Once in the desired position within the nasal cavity, the operator moves the slider backwards which retracts the outer sheath, deploying the End Effector. Using the activation button, the user initiates a bio-impedance check to assess and confirm contact between the End Effector and the treatment area. Once the System confirms contact has been achieved, a subsequent press of the activation button initiates the RF energy delivery cycle. The NEUROMARK® Device is intended for single use and provided sterile (EO).

The NEUROMARK® Device is designed for use with the NEUROMARK® Radiofrequency (RF) Console; it includes features to allow compatibility and authentication once connected, via a flexible interface cable, to the Console.

The NEUROMARK® Console delivers, monitors and controls RF energy to the Device. The Console is mounted on an ergonomic mobile stand for ease of use. The Console includes a Graphical User Interface (GUI) which provides operational instructions for the procedure, directs the user to select nasal cavities for treatment, indicates when the device is in contact with tissue and ready to start treatment, provides status of therapy and indicates when the procedure is complete. The NEUROMARK® Console works in conjunction with software.

11.2 Comparison to Cleared Device

The predicate NEUROMARK® System was cleared by FDA on 22nd October 2021, reference 510(k) [K212666].

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Figure 1: Proposed Modification

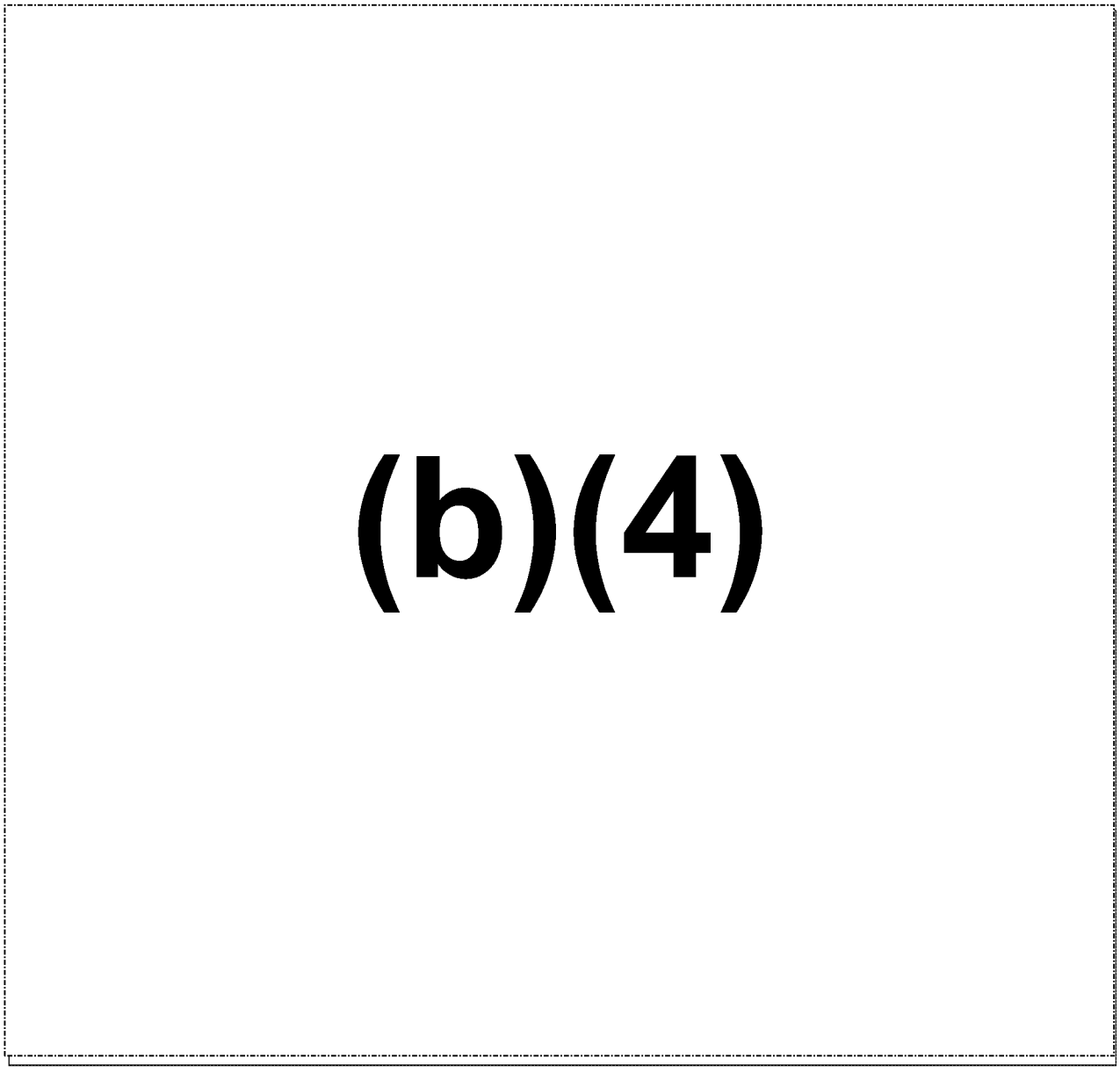

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Table 1: Proposed Modification to Device (Differences are highlighted in **bold**)			
Characteristic	**Predicate NEUROMARK® System [K212666]**	**Subject NEUROMARK® System**	**Reason for Change**
(b)(4)			

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11.3 Changes Made Since the Last Submission

(b)(4)

Table 2: Changes Made Since Last Submission

Description of Change	Documentation of Change
(b)(4)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 2: Changes Made Since Last Submission	
Description of Change	**Documentation of Change**
(b)(4)	

11.4 Intended Use

The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis.

The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

This is the same intended use and indication for use as the previously cleared NEUROMARK® System [K212666].

11.5 Proposed Labeling

(b)(4)

Final draft labels and predicate labels can be found in the following Attachments:

Subject Device Packaging Label	Attachment 07
Predicate Device Current Packaging Label	Attachment 08
Subject Console Packaging Label	Attachment 09
Predicate Console Current Packaging Label	Attachment 10

The IFUs can be found in the following Attachments:

Device Instructions for Use (IFU) Red Line Copy	Attachment 11
Device Instructions for Use (IFU) Clean Copy	Attachment 12
Console Instructions for Use (IFU)	Attachment 13

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject NEUROMARK® System has the same intended use and fundamental scientific technology as the previously cleared, predicate NEUROMARK® System [K212666].

The subject NEUROMARK® System has the following similarities to the predicate device which previously received 510(k) clearance:

- Have the same intended use & labeled indications for use;
- Have the same fundamental scientific technology;
- (b)(4)
- Incorporate the same basic design;
- Use standard medical grade materials;
- Have the same performance specifications and characteristics;
- (b)(4)

The modified subject device does not raise different questions of safety and effectiveness. There are no new risks, and performance testing was completed and demonstrated that the device meets design specifications and performed as intended.

In summary, the subject NEUROMARK® System in this 510(k) submission is substantially equivalent to the predicate NEUROMARK® System [K212666] as shown in the table below.

Table 3: Comparison of Subject Device to Previously Cleared, Predicate Device

Parameter	**Predicate** NEUROMARK® **System [K212666]**	**Subject** NEUROMARK® **System**
FDA Class CFR Regulation Product Code	Class II 21 CFR 878.4400 GEI	**Same**
Intended Use	The NEUROMARK® System is intended for the application of Radiofrequency (RF) energy to create lesions in mucosal tissue in otolaryngological [also known as Ear, Nose and Throat (ENT)] procedures in patients with chronic rhinitis.	**Same**
Indications for Use	The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.	**Same**
Contraindications	None	**Same**
Anatomical location of use	Area of the posterior nasal nerves in the nasal cavity.	**Same**
Target patient population	Adult patients with chronic rhinitis.	**Same**
Principle of operation/Mechanism of action	(b)(4)	
Design configuration		

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Table 3: Comparison of Subject Device to Previously Cleared, Predicate Device		
Parameter	**Predicate** NEUROMARK® **System [K212666]**	**Subject** NEUROMARK® **System**
Patient contacting device materials	(b)(4)	
Energy source	Radiofrequency (RF) energy	**Same**
Operating frequency waveform	465 kHz	**Same**
Total number electrodes	(b)(4)	
Distal leaflets		
Proximal leaflets		
Feedback control	Bioimpedance is monitored during radiofrequency energy delivery.	**Same**
Maximum power output	(b)(4)	
Maximum treatment time		
Thermal lesion characteristics		
Sterile barrier packaging		
Method used to validate sterilization cycle		
Method of sterilization		
Sterility Assurance Level (SAL)		
Shelf life (Device)		
Bench testing (design verification and (b)(4)	(b)(4)	(b)(4)
Biocompatibility	ISO 10993-1	
Software	IEC 60304	
Electromagnetic compatibility	IEC 60601-1-2	
Electrical & thermal safety	IEC 60601-1 and IEC 60601-2-2	

Substantial Equivalence Conclusion

In conclusion, the indications for use and technological characteristics are the same as or equivalent to the predicate device. Performance testing has demonstrated that the device is as safe and effective and that its performance is substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13. RISK ANALYSIS AND VERIFICATION / VALIDATION ACTIVITIES

(b)(4)

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Table 4: Risks Associated with Modifications by Mitigation Activity

(b)(4)

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Table 4: Risks Associated with Modifications by Mitigation Activity

(b)(4)

13.2 Device Specifications

(b)(4)

13.3 Declaration of Conformity

The declaration of conformity with design controls is provided in Attachment 14.

13.4 Summary of Verification / Validation Activities

The design verification and validation tests that were performed because of the risk analysis assessments are listed below:

- Design Verification (DV) Testing (Section 13.4.1)
- (b)(4) Testing (Section 13.4.2)

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- Sterilization (b)(4) (Section 14)
- Biocompatibility Testing (Section 15)
- Console Software Testing (Section 16)
- Electrical & Thermal Safety Testing (Section 17)

13.4.1 Design Verification (DV) Testing

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 5: Design Verification Testing

(b)(4)

All devices passed the acceptance criteria for all the tests performed.

The design verification results are documented in (b)(4) *Design Verification* (b)(4) *Summary Report*.

13.4.2 (b)(4) *Testing*

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

All devices passed the acceptance criteria for all the tests performed.

(b)(4) *Report.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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14. STERILIZATION (b)(4)

Sterilization (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Packaging & Shelf Life

(b)(4)

(b)(4) (Refer to *Section 13.4.1 Design Verification (DV) Testing).*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15. BIOCOMPATIBILITY TESTING

The NEUROMARK® Device is patient contacting and the NEUROMARK® Radiofrequency (RF) Console is non- patient contacting.

According to *ISO 10993-1*, the NEUORMARK® Device is an externally communicating device in limited contact (≤ 24 hours) with tissues of patients. The new patient contacting materials were evaluated for biocompatibility in accordance with *ISO 10993-1*. (b)(4)

(b)(4)

The new materials of the NEUORMARK® Device that *directly* and/or *indirectly* contact the patient are **bolded** in the table below.

(b)(4)

The following table contains a summary of the results of biocompatibility testing conducted by

(b)(4)

Table 8: Biocompatibility Summary Results

Test Performed	Summary of Results by (b)(4)	Results
(b)(4)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 8: Biocompatibility Summary Results

(b)(4)

All devices passed the acceptance criteria for all the tests performed.

The biocompatibility results are documented in (b)(4) (b)(4) *Reports* (b)(4) (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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16. CONSOLE SOFTWARE TESTING

Software Description

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Software Documentation

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

All devices passed the acceptance criteria for all the tests performed.

The software testing results are documented in (b)(4) *Report,* (b)(4) *Report,* (b)(4) *Report,* (b)(4) *Report* and (b)(4) *Report.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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17. ELECTRICAL & THERMAL SAFETY TESTING

Electrical Safety Testing

The impact of the modifications on the electrical safety of the NEUROMARK® System was evaluated and specific clauses of IEC 60601-1 and IEC 60601-2-2 (b)(4)

(b)(4)

Summary results of the electrical safety testing are presented in the table below.

Table 11: Electrical Safety Summary Results

Clause	
IEC 60601-1 (b)(4)	(b)(4)
IEC 60601-1 (b)(4)	
IEC 60601-1 (b)(4)	
IEC 60601-2-2 (b)(4)	
IEC 60601-2-2 (b)(4)	
IEC 60601-2-2 (b)(4)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clause	(b)(4)
IEC 60601-2-2 (b)(4)	
IEC 60601-2-2 (b)(4)	
IEC 60601-2-2 (b)(4)	
IEC 60601-2-2 (b)(4)	

All devices passed the acceptance criteria for all the tests performed.

All applicable requirements of IEC 60601-1 and IEC 60601-2-2 were (b)(4). The subject NEUROMARK® System is electrically safe.

The electrical safety results are documented in test report (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Thermal Safety Testing

The impact of the device modifications on the thermal safety of the NEUROMARK® System was evaluated and the thermal specification (b)(4)

(b)(4)

The thermal safety results are documented in (b)(4) *NEUROMARK System* (b)(4) (b)(4)

Electromagnetic Compatibility

The impact of the device modifications on the electromagnetic compatibility of the NEUROMARK® System was evaluated. (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Hello Karen,

As you know, we are proceeding interactively with your submission for the Neuromark device modifications. I have three interactive questions for you (attached). If you could please provide responses to these questions by Monday, October 10, 2022 by COB that would be helpful. If you need more time, please let me know.

Thanks,
Lindsay

Lindsay DeVries, Au.D., Ph.D.
Scientific Reviewer/Audiology

Ear, Nose, and Throat Devices Team
Center for Devices and Radiological Health
U.S. Food and Drug Administration
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U.S. Food and Drug Administration

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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)*

Device Name
NEUROMARK® System

Indications for Use *(Describe)*
The NEUROMARK® System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions to disrupt posterior nasal nerves in patients with chronic rhinitis.

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)

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