August 26, 2021

Checkpoint Surgical
Ben Cottrill
Product Development Manager
6050 Oak Tree Blvd., Suite 360
Independence, Ohio 44131

Re: K212355
Trade/Device Name: Checkpoint Guardian Intraoperative Lead, Medium, Checkpoint Guardian Intraoperative Lead, Large
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ, ETN
Dated: July 28, 2021
Received: July 29, 2021

Dear Ben Cottrill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1C: Division of 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

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)*
K212355

Device Name
Checkpoint Guardian Intraoperative Lead

Indications for Use *(Describe)*
The Checkpoint Guardian Intraoperative Lead is a single-use, sterile medical device accessory intended to be used with Checkpoint Stimulators to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Special 510(k) Summary

Checkpoint Guardian Intraoperative Lead

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

1 Applicant

Checkpoint Surgical
6050 Oak Tree Blvd., Suite 360
Independence, OH 44131

Contact Person: Ben Cottrill
New Product Development Manager

2 Date Prepared

28/JUL/2021

3 Name of Device

Device Trade Name: Checkpoint Guardian Intraoperative Lead

Device Common Name: Intraoperative Lead

Class: Class II
Regulation Description: Surgical nerve stimulator/locator (874.1820)

Classification Name: Neurosurgical Nerve Locator
Stimulator, Nerve

Product Code: PDQ
ETN

Classification Panel: Neurology

Ear Nose & Throat

4 Predicate Device

Manufacturer	Trade Name	Product Code	Submission #
Checkpoint Surgical	Checkpoint	ETN	K092292

5 Description of Device

The Checkpoint Guardian Intraoperative Leads are single-patient disposable accessories for providing stimulus to a targeted nerve. The accessories are intended for use with any device from the Checkpoint Stimulator/Locator Family. The lead electrode is intended to wrap around nerves that have been surgically exposed, allowing the surgeons to provide hands free stimulus to a targeted nerve.

Model Numbers include:

- REF 9525 Checkpoint Guardian Intraoperative Lead, Medium (7mm nominal diameter)
- REF 9526 Checkpoint Guardian Intraoperative Lead, Large (10mm nominal diameter)

6 Indications for Use

The Checkpoint Guardian Intraoperative Lead is a single-use, sterile medical device accessory intended for use in conjunction with a Checkpoint Stimulator to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.

7 Summary Comparison of Technological Characteristics to Predicate

	Predicate Devices (K092292)	Guardian Intraoperative Lead	Remark
Indications for Use	The Checkpoint® is a single-use device intended to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.	The Checkpoint Guardian Intraoperative Lead is a single-use, sterile medical device accessory intended to be used with Checkpoint Stimulators to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.	Same
Stimulation Electrical Parameters and Waveform	Charge balanced cathodic-first biphasic current-controlled waveform compliant with IEC 60601 2-10:2012+A1:2016.	Charge balanced cathodic-first biphasic current-controlled waveform compliant with IEC 60601 2-10:2012+A1:2016.	Same
Stimulation Electrode Material	304 Stainless Steel	304 Stainless Steel	Same
Stimulation Electrode	Probe	Button contact	SE
Charge Density ($\mu C/cm^2$)	Maximum of 12.7 $\mu C/cm^2$ through minimum contact surface area.	Maximum of 10.5 $\mu C/cm^2$ through minimum contact surface area.	SE
Insulating Material at/around electrode contact	Medical grade polyolefin, MT2000	Pellethane 2363-80A TPU (a thermoplastic polyurethane elastomer), used extensively for both cardiac and deep brain stimulation leads.	SE
Sterilization	Supplied Sterile via validated and monitored ETO cycle	Supplied Sterile via SAME validated and monitored ETO cycle	Same
Shelf Life	2 Years	2 Years	Same
Packaging Config. & Materials	Stimulator with protective probe sleeve in sterile single use Tyvek pouch and paperboard shelf carton.	Lead on HDPE backer card, in same packaging parts with same processes as stimulator.	SE

8 Nonclinical Testing

The Guardian Leads underwent a battery of bench and user tests in accordance with in-house procedures. Design Verification Testing (DVT) conducted on the lead to support this submission demonstrated that all requirements were met including Checkpoint's mechanical and electrical specifications, as well as functionality / performance requirements.

Electrical Safety, general functional testing, and Electromagnetic Immunity / Electromagnetic Compatibility (EMI / EMC) testing for the Checkpoint Stimulator-Locator family was configured and executed in a worst-case configuration to ensure that the stimulation system meets system electrical design specifications and statutory regulations when used in conjunction with associated accessories, including the proposed lead.

Biocompatibility testing was performed on the lead, with all endpoints conforming to limits of BS EN ISO 10993-1:2018 and 2016 FDA guidance titled '*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*"' for its intended use as a limited exposure (<24 hours) externally communicating tissue contacting device Incremental testing on the wire and connector of the subject device was also provided by its manufacturer and certified to have met all relevant biocompatibility endpoints.

Design Analysis and Evaluation Testing evaluated device robustness and correct implementation of the design intent.

A Packaging Assessment was performed to support a determination of substantial equivalence. The same sterile barrier system, sales, and shipping packaging as well as the same labeling stock and inks as the Checkpoint Stimulator Family are used for the proposed lead. The lead was adopted into the same sterilization cycle as the stimulator as per

Electrical Safety Standards applicable to the proposed lead:

- IEC 60601-1:2005 +A12013, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – requirements and tests
- IEC 60601-2-10:2012+A1:2016, Medical Electrical Equipment- Part 2.10: Particular Requirements for Safety and Essential Performance of Nerve & Muscle Stimulators

Standards used to perform Biocompatibility Testing:

- EN ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- BS EN ISO 10993-7:2008, Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
- EN ISO 10993-10:2013, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- BS EN ISO 10993-11:2018, Biological evaluation of medical devices – Tests for systemic toxicity

Results of this testing provide reasonable assurance that the proposed device design meets the

performance requirements and performs as intended.

9 Conclusions

The Checkpoint Guardian Intraoperative Leads have the same indication for use and share similar technological characteristics with their predicate devices, for which they are accessories. Any technological differences between the predicate device (K092292) and the Checkpoint Guardian Intraoperative Leads have been analyzed in terms of risks and addressed through performance testing which demonstrates that the Intraoperative Lead meets its intended use. There are no new concerns around safety or effectiveness. Thus, the leads have been shown to be substantially equivalent to legally marketed predicate devices.