February 2, 2023

Prolira B.V.
% Dr. Paul Manberg
Corolla Clin/Reg Consulting
481 Spindrift Trail #696
Corolla, North Carolina 27927

Re: K222671
Trade/Device Name: DeltaScan Patch
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 25, 2022
Received: September 6, 2022

Dear Paul Manberg:

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,

Jay R. Gupta -S

Jay Gupta
Assistant Director
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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)*
K222671

Device Name
DeltaScan Patch

Indications for Use *(Describe)*
The DeltaScan Patch is applied directly to the patient's skin to record EEG signals.

The DeltaScan Patch is dedicated and only intended to be used in combination with the DeltaScan Monitor (K222680) through a proprietary connector design.

Please refer to the Instructions for Use and the Instructions for Use on the Primary packaging of the DeltaScan Patch for more information.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21 CFR 807.92.

I. SUBMITTER

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Date Prepared: August 25, 2022, date updated 05-Jan-2023

II. DEVICE

Name of Device: DeltaScan Patch
Common or Usual Name: DeltaScan Patch
Classification Name: Cutaneous electrode (21 CFR 882.1320).
Regulatory Class: II
Product Code: GXY

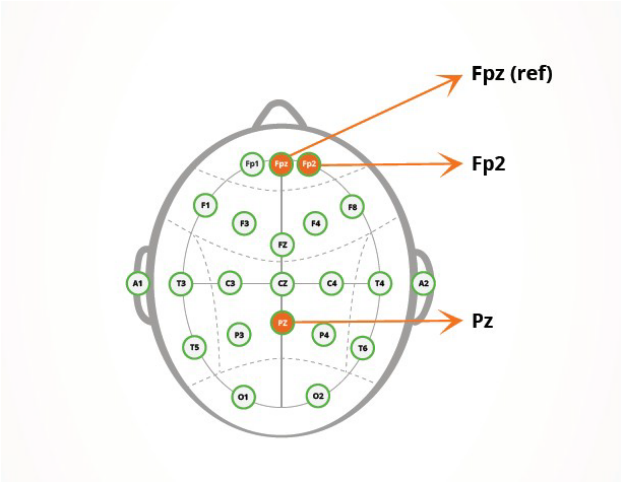
III. PREDICATE DEVICE

Name	Manufacturer	510(k) #
Covidien BIS Sensors (BIS Quatro Sensor, BIS Extend, BIS Pediatric Sensor, BIS Bilateral Sensor)	COVIDIEN	K143506

IV. DEVICE DESCRIPTION

The DeltaScan Patch is a single use EEG electrode Patch, used exclusively with the DeltaScan Monitor. The DeltaScan Patch is used with the DeltaScan Monitor to enable the acquisition of EEG signals. The DeltaScan Monitor provides signal analysis technology intended for use as an adjunct to clinical judgment.

The DeltaScan Patch is used to collect EEG signals from two electrode locations see Figure 5-1 DeltaScan Patch Electrode Locations.



- The 1st electrode is placed on or close to Pz (on the crown of the head)
- a second electrode on or close to Fp2 (above the patient's right eyebrow
- a third (Reference) electrode on or close to Fpz (above the nose on the forehead)

Pz, Fp2 and Fpz refer to defined EEG electrode locations in the standard 10/20 EEG setup

Figure 5-1 DeltaScan Patch Electrode Locations

For a depiction of the main components, see Figure 5-2 below:

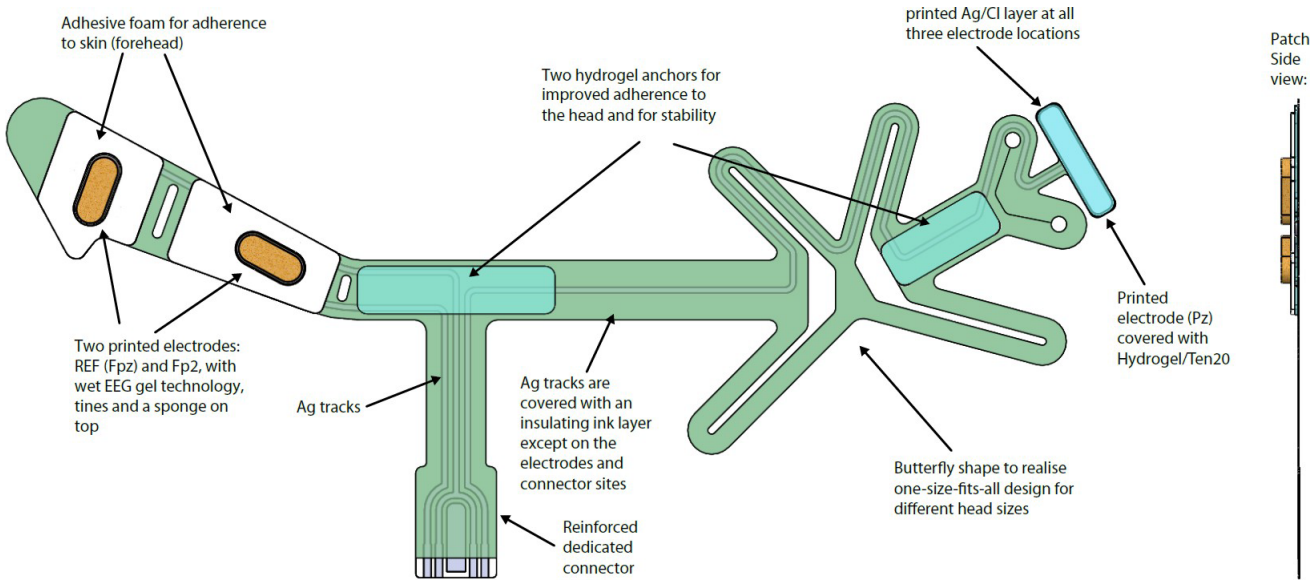


Figure 5-2 Product overview

In designing the DeltaScan Patch, the International 10-20 System was used as a basis for electrode placement. Two recording electrodes are placed on the scalp at the Fp2 and Pz locations, while the reference electrode is placed at the Fpz location, see Figure 5-1 DeltaScan Patch Electrode

Locations above. The electrodes are individually packaged and pre-gelled. The DeltaScan Monitor should only be used in combination with a DeltaScan Patch, see Figure 5-3.

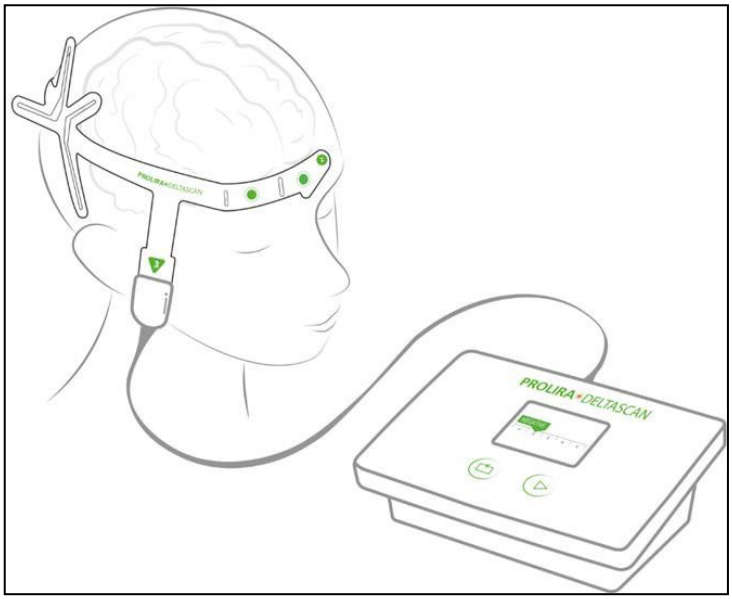


Figure 5-3: Artist impression of the DeltaScan Monitor used with a DeltaScan Patch

V. INDICATIONS FOR USE

The DeltaScan Patch is applied directly to the patient's skin to record EEG signals.

The DeltaScan Patch is dedicated and only intended to be used in combination with the DeltaScan Monitor (K222680) through a proprietary connector design.

Please refer to the Instructions for Use and the Instructions for Use on the Primary packaging of the DeltaScan Patch for more information.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Like the predicate, the DeltaScan Patch is applied directly to the patient's skin to enable recordings of EEG signals.

The BIS Sensor with submission number K143506 is suggested as the most appropriate predicate device.

A technology comparison is provided in **Table 5-1** below.

Table 5-1 technology comparison

BIS Sensor	**DeltaScan Patch**
Intended Use	
Electrode, Cutaneous Electrode	Electrode, Cutaneous Electrode
Indications for Use	
Electrode that is applied directly to a patient's skin to record EEG signals. Note: used in conjunction with Covidien BIS Monitors.	The DeltaScan Patch is an electrode that is applied directly to a patient's skin to record EEG signals. The DeltaScan Patch is intended to be used in combination with the DeltaScan Monitor (K222680) through a proprietary connector design. Please refer to the Instructions for Use on the Primary packaging of the DeltaScan Patch and the Instructions for Use of the DeltaScan Monitor for more information.
LIMITATIONS For prescription use only. Single use Only to be used with the BIS Monitor Refers to the labeling for a more complete list of Warnings, Precautions and Contraindications.	LIMITATIONS For prescription use only. Single use Only to be used with the DeltaScan Monitor Refers to the labeling for a more complete list of Warnings, Precautions and Contraindications.
Primary EEG Feature/Electrode position	
It is a low impedance, single patient use, disposable electrode sensor	It is a low impedance, single patient use, disposable electrode sensor
The "zipprep" design is constructed using flexible tine disks placed in pockets on a polyethylene basepad. A polyurethane foam disk and hydrogel is placed over the tines. The basepad has a medical grade pressure sensitive adhesive for adhering to the skin. A mylar substrate with conductive silver / silver chloride ink circuit is adhered to the other side of the base pad. The flexible tines, surrounded by hydrogel, are used to part the outermost layer of skin. While the flexible tines part the skin, hydrogel flows around the tines and forms a conductive bridge with the skin. The silver / silver chloride circuit provides signal continuity from each electrode (gel/tine/foam) to the monitor. A polyester insulation is used to restrict electrical contact to the electrode area.	**Equivalent** The DeltaScan Patch electrode buildup (see Figure 5-2) consists of: - a polyurethane foam sponge with conductive wet EEG gel and tines to reduce impedance - a carrier (substrate) of flexible PET foil (Melinex) - a medical grade adhesive foam around the electrodes for adherence to the skin - the conductive silver tracks and silver /silver chloride electrodes provide signal continuity from the electrode (gel, foam, tine) to the monitor - isolation layer covering the silver ink tracks of the printed electrodes is used to restrict electrical contact to the electrode area - hydrogel anchors for improved adherence to the head and for stability - the reinforced connector is a dedicated mechanism to interface with the Monitor.

BIS Sensor	DeltaScan Patch
The body of the sensor houses three (3) electrodes which are placed on the forehead, and a fourth electrode placed over the temple area.	**Equivalent** The body of the sensor houses two (2) electrodes which are placed on the forehead, and a third electrode at the area on the crown of the head (Pz location).
Software	
N/A	N/A
Device Output	
The sensor collects EEG signals and these are used to calculate the Bispectral Index (BIS) value by the BIS Monitor.	**Equivalent** The sensor collects EEG signals and these are used to calculate the DeltaScan Output by the DeltaScan Monitor.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the DeltaScan Patch was assessed in accordance with the FDA's guidance document titled, "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process'", June 16, 2016.

The DeltaScan Patch is only worn by hospitalized adult patients (*e.g.*, in the intensive care unit (ICU), cardiothoracic postoperative ward or geriatric traumatology ward) (see Figure 5-3) during a DeltaScan measurement[1]. Such measurement potentially takes place once per 8 hours and has a duration of approx. 4 minutes (worst case 3x 10 minutes per 24 hours) and potentially on 3 to 5 consecutive days. Therefore, the DeltaScan Patch is a so called "surface contacting device" (contact with intact skin) with a limited duration (<24 hours each day).

As can been seen in Figure 5-2, the parts of the DeltaScan Patch that are in direct contact with the patient's skin during a measurement are the materials that construct the electrodes (the Sponge (Polyurethane foam), Adhesive Foam, Tines, Wet gel electrolyte, Hydrogel PROMEON 863B, Green isolation layer)).

All parts of the DeltaScan Patch R2 with REF 009.000.B that are directly in contact with the patient's skin have passed the acceptance criteria defined per ISO 10993-1:2018 requirements.

[1] DeltaScan Monitor is Indicated for adults over 60 years of age.

Electrical safety and electromagnetic compatibility (EMC)

In accordance with the EN ISO 60601-1, the use of the DeltaScan Patch does not depend on essential performance. The DeltaScan Patch is not considered Medical Electrical Equipment as defined by the EN ISO 60601-1.

Software verification and validation testing

N/A as the DeltaScan Patch does not contain software.

Mechanical testing

- The labels on the packaging were tested to verify be legible, durable, compliant with regulations, and compatible with the packaging.
- The packaging was tested to verify to be compatible with the labeling, and can be shipped without damage.

The 'Label and IfU review report' is provided in this 510(k) and the Shipping Validation Report DeltaScan Patch is provided in this 510(k).

Shelf life

The DeltaScan Patch has a stated shelf life of 9 months. These 9 months are mainly based on the degradation of the two frontal electrodes, being the most critical part for shelf life of the DeltaScan Patch. This is verified and documented in the Verification Report based on accelerated aging.

Real time aging is still in progress and may in future demonstrate a longer shelf life.

Clinical Studies

The Verification Report provides sufficient proof that it transfers the electrical signals as intended. No dedicated clinical study is needed to validate the device performance.

The data in the Verification Report for the DeltaScan Patch shows that it performs as intended, is safe and effective for its intended use, and provides similar safety and effectiveness results to the predicate device.

VIII. CONCLUSION

Based on the intended use, technological characteristics, and performance data provided in this premarket notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.