510K Premarket Notification – Status Review

1/21/2022

Victor R. Lange, PhD, JD
Invenio Medical, Inc.
27671 Aquamarine
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UNITED STATES

Dear Victor R. Lange, PhD, JD:

Thank you for your recent inquiry pertaining to the status of your submitted documentation. The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submitted documentation and we have assigned a 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 above letterhead address. 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 department which was provided to you on prior correspondence

CONTROL: C1A2788761

Received: 1/21/2022
Applicant: Invenio Medical, Inc.
Device: AptaSure MRSA

Our records indicate that the following preliminary criteria have been met:

- Your product is 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 the 510k document control.
- Your 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)):
- Your submission contains an Indications 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/regulatoryinformation/search-fda-guidance-documents/alternative-certainprescription-device-labeling-requirements.)
- Your submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l).
- Your submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank

- Your submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance
- 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.
- The submission addresses device description recommendations outlined in the device-specific guidance.
- 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.
- Your submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory
- 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).
- Your submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).
- 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."
- 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.

Our records indicate that we are performing final validation of the following:

- Each relevant endpoint for the device (as identified in devices 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

- 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.

    - Our analysis has validated your compliance with the minimum referenced standards.

We will notify you when the review of this document has been completed or if any additional information is required.

Sincerely yours,

Center for Devices and Radiological Health

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