October 15, 2025

PainChek Limited
% Caleb Ng
QA/RA Manager
KD&A Pty. Ltd.
27 Belgrave Street, Suite 301
Manly, NSW 2095
Australia

Re: DEN240073
Trade/Device Name: PainChek Adult
Regulation Number: 21 CFR 882.1472
Regulation Name: Pain assessment software in non-communicative adults
Regulatory Class: Class II
Product Code: SGB
Dated: November 15, 2024
Received: December 11, 2024

Dear Caleb Ng:

This letter corrects our previous classification order, dated October 6, 2025, to correct the regulation number.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the PainChek Adult, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> PainChek Adult is an observational pain assessment software application used to assist healthcare professionals in the assessment of pain in non-verbal patients who have been diagnosed with moderate to severe dementia and who are living in nursing homes. Specifically, PainChek Adult is intended to be used by trained medical doctors, nurses, licensed practical and vocational nurses, certified nursing assistants, clinical psychologists, physical therapists and occupational therapists to assess pain in the indicated population.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the PainChek Adult, and substantially equivalent devices of this generic type, into Class II under the generic name pain assessment software in non-communicative adults.

FDA identifies this generic type of device as:

> **Pain assessment software in non-communicative adults.** Pain assessment software in non-communicative adults is a prescription-only device that combines information from clinical pain domains to produce an output indicative of a patient's current level of pain in conscious adult patients

who are unable to communicate their current pain level. This device is intended for adjunctive use and not intended as a stand-alone diagnostic or prognostic tool.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 11, 2024, FDA received your De Novo requesting classification of the PainChek Adult. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the PainChek Adult into Class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the PainChek Adult can be classified in Class II with the establishment of special controls for Class II. FDA believes that Class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Device failure or incorrect analysis leading to: • False positives or falsely high device pain outputs resulting in inappropriate treatment of a patient's pain • False negatives or falsely low device pain outputs resulting in failure to treat a patient's pain	Clinical performance testing Software verification, validation, and hazard analysis Labeling
Use error or misinterpretation of results resulting in: • False positives or falsely high pain assessments or device pain outputs resulting in inappropriate treatment of a patient's pain • False negatives or falsely low pain assessments or device pain outputs resulting in failure to treat a patient's pain	Human factors/usability assessment Labeling

In combination with the general controls of the FD&C Act, the pain assessment software in non-communicative adults is subject to the following special controls:

(1) Clinical performance validation testing acquired under anticipated conditions of use must demonstrate that the device performs as intended when used to analyze data from the intended patient population. Testing must demonstrate the accuracy and test-retest reliability for assessment of pain as compared to a relevant clinical reference standard. Objective performance measures must be reported.

(2) Software verification, validation, and hazard analysis must be provided. Software documentation must include a detailed, technical description of the model/algorithm(s), and algorithm input(s) and output(s).

(3) Human factors/usability assessment must demonstrate that the intended user(s) in the intended use environment can correctly use the device and interpret the device output, based solely on reading the instructions for use.

(4) Labeling must include:

(i) A detailed summary of the clinical performance testing methods, including results of the performance testing for tested performance measures/metrics, selection criteria, and the patient demographics;

(ii) A description of the patient population that was used in development or training of the device algorithm/model;

(iii) Device limitations or subpopulations for which the device may not perform as expected or for whom the device has not been validated;

(iv) A statement that the device is not a stand-alone diagnostic tool, and that the device output should only be interpreted in the context of all available clinical information; and

(v) Information for interpretation of the device output detailing the risks associated with misinterpretation of the device output.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a Class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the pain assessment software in non-communicative adults they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Patrick Antkowiak, Ph.D., at 240-402-3705 or Patrick.Antkowiak@fda.hhs.gov.

Sincerely,

XIAOLIN
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For David McMullen, M.D.
Director
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health