June 23, 2025

Vipamat Sarl
% Sarah Robbins
Senior Quality Manager
Rook Quality Systems LLC
1155 Mount Vernon Hwy
Suite 800
Dunwoody, Georgia 30338

Re: K251570
Trade/Device Name: Hippocampe Marathon and Trail
Regulation Number: 21 CFR 890.3880
Regulation Name: Special Grade Wheelchair
Regulatory Class: Class II
Product Code: IQC
Dated: May 16, 2025
Received: May 22, 2025

Dear Sarah Robbins:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Physical Medicine Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251570

Please provide the device trade name(s).

Hippocampe Marathon and Trail

Please provide your Indications for Use below.

The Hippocampe Marathon and Trail is indicated to provide mobility to persons restricted to a seated position on various terrains, including footpaths and trails.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K251570

510(k) Summary

Prepared on: 2025-06-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Vipamat Sarl
Applicant Address	3 Rue Gustave Eiffel Ploemeur 56270 France
Applicant Contact Telephone	+33297862487
Applicant Contact	Mr. Vincent Leroy
Applicant Contact Email	contact@vipamat.com
Correspondent Name	Rook Quality Systems LLC
Correspondent Address	1155 Mount Vernon Hwy Suite 800 Dunwoody GA 30338 United States
Correspondent Contact Telephone	803-338-6041
Correspondent Contact	Ms. Sarah Lacey Robbins
Correspondent Contact Email	Sarah.Robbins@rookqs.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Hippocampe Marathon and Trail
Common Name	Special grade wheelchair
Classification Name	Wheelchair, Special Grade
Regulation Number	890.3880
Product Code(s)	IQC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K051709	Hippocampe Wheelchair	IQC

Device Description Summary

21 CFR 807.92(a)(4)

The Hippocampe Marathon and Trail is an occupant or care provider propelled manual operated wheelchair. The Hippocampe Marathon and Trail is designed for everyday use as well as recreational activity such as running and trail running, in the following environments:
Indoors and outdoors;
Over smooth, rough, and uneven ground;
Over soft and hard surfaces;
Over small obstacles, like door jams; and
Up, down and across slopes.

The Hippocampe Marathon and Trail is a three-wheel triangular wheelchair comprised of bent aluminum tubing frame that are bent, joined, fastened, and/or coupled with connectors to form a frame. The frame consists primarily of a lower frame, adjustable height seat

back frame, adjustable headrest, push bar and push bar frame, tubing clamp connectors, footrest, arm rests, rear axle assembly, and front fork and axle assembly. Once assembled, the wheelchair frame is fixed. The recline of the seat back frame can be adjusted with depth adjustment screws at the base of the seat back frame. The upholstery is attached to the frame using nylon straps and buckles and is fire resistant. A rigid plastic open basket-like structure located in the middle of the lower frame and behind the front fork assembled provides the occupant a footrest and has a removable layer of foam. On the push bar are control levers for disc brakes of the rear wheels which are operated by the occupant's care provider. The disc brakes also act as parking brakes and are activated by the care provider.

The Hippocampe Marathon and Trail can be easily assembled and disassembled for stowage or storage by detaching the lower frame of the armrest and folding the seat back frame forwards. The wheelchair is available in three sizes: medium, large and extra-large. The maximum weight capacity of Hippocampe Marathon and Trail is 220 lbs.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Hippocampe Marathon and Trail is indicated to provide mobility to persons restricted to a seated position on various terrains, including footpaths and trails.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for Use and Intended use
The Hippocampe Marathon and Trail is indicated to provide mobility to persons restricted to a seated position up to a weight capacity of up to 220 lb. The predicate device has a similar intended use, with the difference being a higher weight capacity of 286 lb.
Both the subject and predicate device have the same indicated use of providing mobility to persons restricted to a seated position indoor and outdoor use, on various terrain, surfaces, obstacles and slopes. The standard version of the predicate device has a wider scope of indication for use, including terrain such as sand, snow, and in water. The more limited indication of use of terrain of the subject device for footpaths and trails does not raise any questions in the safety or performance of the subject device.
The indications for use of the subject device are substantially equivalent to the predicate device. The difference in weight capacity does not raise any questions in the safety or performance of the subject device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device Hippocampe Marathon and Trail wheelchair and predicate device Hippocampe Wheelchair (K051709) are both unpowered three-wheeled design mechanical wheelchairs comprised of aluminum tubing fastened together.

Device Characteristics
Frame
The subject and predicate device share the same three-wheel frame design, with armrests that are detachable, adjustable headrests, height adjustable backrest, and pushbar.
The subject device has a lower weight capacity of 220 lbs compared to the 286 lbs of the predicate device. The weight capacity is indicated on the subject device's label and within the subject device's IFU.
The subject device and predicate devices can be disassembled for storage and transportation by unfastening the armrests and pivoting the seat back frame forwards

Brakes
The subject device also has disc brakes that are operable by the care provider for slowing down the wheelchair while in motion and as parking brakes while the predicate device only has parking brakes. Braking performance of both devices have been evaluated in accordance with ISO 7176-3.

Upholstery
Both the subject and predicate devices have upholstery that fasten to the wheelchair frame to provide support for the occupant when sitting. The subject device's seating upholstery is supported by a rigid frame while the primary predicate device is a sling-style. Both the upholsteries of the subject and primary predicate devices are fire/ignition resistant.

Care Provider Propulsion
Both the subject and predicate devices are intended to be able to have the occupant pushed by a care provider. The subject device and predicate devices have substantially designs which utilize the wheelchair frame or push bar to enable care provider pushing.

Accessories
The predicate device has accessories that enable usage on a wider range of terrain compared to the subject device, such as on sand, snow, and in water. The subject device has optional trail wheels which are similar to the standard wheels of the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical validation testing and evaluations were performed to demonstrate the safety and effectiveness of the device. The following tests were performed:

- ISO 7176-1 Third edition 2014-10-01 - Wheelchairs - Part 1: Determination of static stability
- ISO 7176-3 Third edition 2012-12-15 - Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-5 Second edition 2008-06-01 - Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
- ISO 7176-7 First Edition 1998-05-15 Wheelchairs - Part 7: Measurement of seating and wheel dimensions
- ISO 7176-8 Second edition 2014-12-15 - Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
- ISO 7176-11 Second edition 2012-12-01 Wheelchairs - Part 11: Test dummies
- ISO 7176-13 First edition 1989-08-01 - Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
- ISO 7176-15 First edition 1996-11-15 - Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
- NF ISO 7176-16:2014 Wheelchairs – Part 16 : Resistance to ignition of postural support devices
- NF ISO 7176-22 Second edition 2014-09-01 Wheelchairs - Part 22: Set-up procedures

Not applicable

The bench testing performed demonstrates that the Hippocampe Marathon and Trail is substantially equivalent in safety, effectiveness, and performance to the predicate device.