December 2, 2024

Synthon Hispania S.L.
℅ Rebecca (Becky) Welton
Senior Consultant, RA
Lachman Consultant Services, Inc.
1600 Stewart Avenue, Suite 604
Westbury, New York 11590

Re: K243232
Trade/Device Name: GripMate
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe needle introducer
Regulatory Class: Class II
Product Code: KZH
Dated: October 9, 2024
Received: October 9, 2024

Dear Rebecca (Becky) Welton:

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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K243232

Device Name
GripMate™

Indications for Use *(Describe)*
The GripMate™ autoinjector is intended for use with Sun Pharma's glatiramer acetate 20 mg/mL and 40 mg/mL prefilled syringes (a 1 mL BD Hypak Biotech glass syringe, containing a ½" fixed needle of 29G, and drug product solutions with a viscosity between 1.7 and 2.3 mPas). The GripMate™ autoinjector is a reusable injection device for patients with multiple sclerosis age 18 and older for the subcutaneous injection of Sun Pharma's glatiramer acetate 20 mg/mL and 40 mg/mL prefilled syringes.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**K243232 510(k) SUMMARY**

| **APPLICANT** |
|---|
| Synthon Hispania S.L.<br>Calle Castello<br>1 Poligono Las Salinas<br>Sant Boi de Llobregat, Barcelona, 08830<br>Spain<br><br>Contact Person: Mrs. Ana Miralles<br>Telephone: +34936401516<br>Email: ana.miralles@synthon.com<br>Date Prepared: November 21, 2024 |
| **CORRESPONDENT** |
| Lachman Consultant Services, Inc.<br>1600 Stewart Avenue, Suite 604<br>Westbury NY 11590<br>United States<br><br>Contact Person: Rebecca (Becky) Welton<br>Alternate Contact Person: Jennifer Leaming<br>Telephone: 516-222-6222<br>Email: LCSReg@lachmanconsultants.com |
| **DEVICE NAME** |
| Name: GripMate™<br>Common name: Syringe needle introducer<br>Classification name: Introducer, Syringe Needle<br>Regulation number: 880.6920<br>Product codes(s): KZH |
| **LEGALLY MARKETED PREDICATE DEVICES** |
| Device name: Lobster Auto-<br>Injector 510(k) number: K124026<br>Product codes(s): KZH |

**DEVICE DESCRIPTION SUMMARY**

The GripMate™ is a non-sterile, reusable, spring-loaded injection device. The device consists of two subassemblies into which the syringe is loaded and connected together to form the delivery system for self-injection. The device does not have any fluid path and does not have any contact with the drug contained within the syringe. The user has the option to adjust the needle extension using the device Needle Hider Front adjuster feature. Injection occurs upon the activation of a trigger button which drives the syringe in a three-step sequence which includes needle penetration, injection and needle cover. Once the injection is completed the device provides visual indication to confirm that the full drug dose has been delivered.

**INTENDED USE / INDICATIONS FOR USE**

The GripMate™ autoinjector is intended for use with Sun Pharma's glatiramer acetate 20 mg/mL and 40 mg/mL prefilled syringes (a 1 mL BD Hypak Biotech glass syringe, containing a ½" fixed needle of 29G, and drug product solutions with a viscosity between 1.7 and 2.3 mPas). The GripMate™ autoinjector is a reusable injection device for patients with multiple sclerosis age 18 and older for the subcutaneous injection of Sun Pharma's glatiramer acetate 20 mg/mL and 40 mg/mL prefilled syringes.

**INDICATIONS FOR USE COMPARISON**

GripMate™ autoinjector has a similar intended use and the same principle of operation as the Lobster autoinjector.

**TECHNOLOGICAL COMPARISON**

The GripMate™ autoinjector is substantially equivalent to the predicate device. Both devices are designed for self-administered subcutaneous injection of FDA-approved drugs, using a spring-loaded powered mechanism. They share many of the same features such as spring-loaded powered mechanism, safety mechanisms, biocompatibility, and usability characteristics. The primary differences lie in the specific applications and injection depth settings; the GripMate™ is tailored for Sun Pharma's glatiramer acetate, includes two viewing windows for better visual feedback, and has audio feedback for injection completion, enhancements that improve user usability and interaction. The GripMate™ has two injection depth settings (6 and 8 mm), whereas the predicate device has injection depth settings of 4, 6, 8 and 10 mm.

Additionally, both devices conform to ISO 13485 standards and have the same classification under 21 CFR § 880.6920. The GripMate™ slight differences and additional features such as audio feedback are considered are aimed at enhancing usability without altering the fundamental technology or principles of operation. These updates ensure that the GripMate™ provides improved user feedback and ease of use while maintaining the core functionalities and safety measures of the predicate Lobster device.

| **Specification/ Characteristic** | **Predicate Device**<br>Lobster | **Candidate Device**<br>GripMate™ | **Comparison** |
|---|---|---|---|
| Manufacturer | Sandoz Inc. | Synthon | Substantially equivalent (SE)<br>Manufacturers QMS operate under ISO 13485 |
| 510(k) | k124026 | k243232 | n/a |
| Product code | KZH<br>Syringe needle introducer | KZH<br>Syringe needle introducer | Identical |
| Regulation number | 21 CFR § 880.6920 | 21 CFR § 880.6920 | Identical |
| Classification panel | General Hospital (80) | General Hospital (80) | Identical |

| | | | |
|---|---|---|---|
| Over-the-Counter (OTC) and/or Prescription (Rx Only) | Rx only and Over the Counter | Rx only | SE Validated via human Factors |
| Intended use | For a self-administered subcutaneous injection of FDA approved drugs | For a self-administered subcutaneous injection of Sun Pharma's glatiramer acetate 20 mg/mL and 40 mg/mL prefilled syringes | SE Scope is for self-administration of a specific FDA approved product |
| Indications for use | The Lobster device is intended for use with a 1mL glass syringe, containing a fixed needle of 27G to 29G gauge, and drug product solutions with a viscosity between 1 and 4 mPas. The Lobster auto-injector is a reusable injection device for the subcutaneous injection of FDA approved drugs. | The GripMate™ autoinjector is intended for use with Sun Pharma's glatiramer acetate 20 mg/mL and 40 mg/mL prefilled syringes (a 1 mL BD Hypak Biotech glass syringe, containing a ½" fixed needle of 29G, and drug product solutions with a viscosity between 1.7 and 2.3 mPas). The GripMate™ autoinjector is a reusable injection device for patients with multiple sclerosis age 18 and older for the subcutaneous injection of Sun Pharma's glatiramer acetate 20 mg/mL and 40 mg/mL prefilled syringes. | SE Scope is for self-administration of a specific FDA approved product |
| Fundamental scientific technology | Handheld self-injection system | Handheld self-injection system | Identical |
| Principle of operation | Spring-loaded powered mechanism is used to insert a hypodermic needle attached to a pre-filled syringe through the patient's skin and to inject the drug | Spring-loaded powered mechanism is used to insert a hypodermic needle attached to a pre-filled syringe through the patient's skin and to inject the drug | Identical |
| Environment of use | At home, for single patient use only | At home, for single patient use only | Identical |
| Device type | Hand-held, non-sterile, reusable | Hand-held, non-sterile, reusable | Identical |
| Syringe type | Glass, pre-filled | Glass, pre-filled | Identical |
| Syringe size | 1.0 ml | 1.0 ml | Identical |
| Fixed or removable needle | Fixed needle | Fixed needle | Identical |
| Dose system | One injection per syringe | One injection per syringe | Identical |
| End of dose indication | Visual | Visual | Identical |
| Trigger button for firing | Yes | Yes | Identical |
| Fixed dose | Yes | Yes | Identical |
| Needle hidden before injection | Yes | Yes | Identical |

| | | | |
|---|---|---|---|
| Safety lock to prevent accidental activation | Yes | Yes | Identical |
| Needle shield removal | Yes | Yes | Identical |
| Biocompatibility | Conforms to ISO 10993 | Conforms to ISO 10993 | Identical |
| Overall device length,(mm) | 226.0 | 224.0 | SE<br>Validated via human Factors |
| Overall device width- at widest point (mm) | 31.0 | 34.0 | |
| Needle extension penetration | Variable, 4-10 mm | Variable, 6-8 mm | SE<br>To mitigate the risk of inadequate injection the 4 and 10 mm setting were not incorporated in the candidate device. Verified through design verification. |
| Injection time as indicated in labeling | ≤ 15 sec | ≤ 15 sec | Identical |
| Device state-visible feedback | One viewing window | Two viewing windows | SE<br>Two large feedback windows on the candidate device is usability improvement which enables the user to see the injection status from multiple angles. Validated via human Factors |
| Device state-audible feedback | None | Click at activation. Second click at injection completion. | SE<br>Audio feedbacks feature for candidate device is usability improvement which provides an audible feedback to the user about the injection completion status. |
| Use-life | Two years after first use | Two years after first use | Identical |
| Needle extension tolerance (mm) | Unknown | ± 1.5 | n/a |
| Trigger button activation force (N) | Unknown | 2-8 | n/a |
| Pre-injection pushing force (N) | Unknown | 3-12 | n/a |
| Trigger button override force (N) | Unknown | > 80 | n/a |
| Syringe loading force (N) | Unknown | ≤ 27.1 | n/a |
| Needle shield remover force (N) | Unknown | ≤ 35 | n/a |

**PERFORMANCE DATA / NONCLINICAL TESTING**

Design verification and performance testing have been conducted to verify GripMate™ meets design specifications and performs as intended.

**Functional Testing**

Functional evaluation was conducted in-house in accordance with the FDA recognized International Standards ISO 11608-1 "Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems", ISO11608-5 "Needle-Based Injection Systems for Medical Use - Requirements and Test

Methods - Part 5: Automated functions" and the recommendations included in the FDA guidance document, Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products". Per standard requirements an environmental testing (e.g., temperature cycling, drop testing, vibration testing etc.) preceded the functional testing of the GripMate™.

Testing to assess the functionality of GripMate™ included:

- Verification of dose accuracy
- Injection time
- Needle extension
- Safety features
- Indicators features

Testing to assess the mechanical specifications of GripMate™ included:

- Force required to actuate the injector
- Force required to operate the Needle Shield Remover
- Force required to override the safety mechanism
- Force required to load the pre-filled syringe
- Torque required to assemble/disassemble the injector
- Torque required to operate Needle Hider Front Adjuster
- Load testing on individual device components

**Environmental Conditions Testing**

The environmental conditions and packaging integrity evaluation for GripMate™ was conducted by a certified testing laboratory in accordance with the recognized by the FDA ASTM D4169 "Standard Practice for Performance Testing of Shipping Containers and Systems" and in-house in accordance with the International Standard ISO 11608-1 "Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems". The outcome of the testing demonstrates that the candidate device performance and reliability is not affected by the environmental conditions specified by the standards at the time of storage, use testing or during transportation.

**Shelf Life and In-Use Life Testing**

Candidate device shelf life and in-use life evaluation was conducted in accordance with the ISO 11608-1 "Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems" and ASTM F1980 "Standard Guide For Accelerated Aging of Sterile Barrier Systems For Medical Devices". Shelf-life and in-use life claims were established per outcome of the accelerated stability studies and use life testing. A real-time protocol was evaluated to assure on-going stability. The use life of the device was simulated by operating the device 1.5 times its expected number of actuations during the device's planned use life and taking into consideration the intended use of device as described in the device Instructions for Use. The successful completion of functionality and reliability testing of the device supports in-use life claim of two years after first use.

In the non-clinical bench testing the following solutions were tested: glatiramer acetate 20 mg, glatiramer acetate 40 mg, clexane forte and 34 % sucrose solution.

**Biocompatibility Testing**

GripMate™ safety with regard to the biocompatibility was concluded based on the interpretation of biological evaluation data and overall biological safety assessment. The biocompatibility testing was performed by a certified testing laboratory in accordance with FDA recognized International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process."

**Human Factors Testing**

The GripMate™ design and Instructions for Use (IFU) were evaluated in a simulated use Human Factors study in accordance with AAMI / ANSI HE75, Human Factors Engineering - Design Of Medical Devices and the recommendations included in the FDA guidance document, "Applying Human Factors and Usability Engineering to Medical Devices". The study demonstrates that the use-related risks are adequately mitigated by the design and labelling of the device.

**Summary**

Based on the performance data, the GripMate™ was found to perform similarly to the predicate device.

| **CONCLUSION** |
| --- |
| The GripMate™ is substantially equivalent to the predicate device. |