August 28, 2025

Ypsomed AG
Johannes Schmid
Regulatory Manager
Brunnmattstrasse 6
Burgdorf, Bern 3401
Switzerland

Re: K243901
Trade/Device Name: SmartPilot YpsoMate NS-A2.25
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: QOG
Dated: July 29, 2025
Received: July 29, 2025

Dear Johannes Schmid:

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,

for Kyran R. Gibson -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)*
K243901

Device Name
SmartPilot YpsoMate NS-A2.25

Indications for Use *(Describe)*
The SmartPilot YpsoMate NS-A2.25 is indicated for use with the compatible disposable autoinjector to capture and record injection information that provides feedback to the user.

SMARTPILOT MODEL	DRUG MANUFACTURER	DRUG NAME	BRAND NAME
SmartPilot YpsoMate NS-A2.25	Novartis/Sandoz	Secukinumab	Cosentyx

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.

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510(k) Summary Complying with 21 CFR 807.92

K243901 510(k) Summary

I. SUBMITTER

YPSOMED AG
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Burgdorf Bern, CH CH-3401
Switzerland

Phone: +41 34 424 41 11
Fax: +41 34 424 41 22

Contact Person: Johannes Schmid Date Prepared: August 28, 2025

II. DEVICE

Name of Device: SmartPilot YpsoMate NS-A2.25
Common or Usual Name: Injection Data Capture Device
Classification Name: Piston Syringe (21 CFR 880.5860)
Regulatory Class: II
Product Code: QOG

III. PREDICATE DEVICE

Mally Injection Pen Adapter, K222689
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The SmartPilot YpsoMate NS-A2.25 is an optional, battery operated, reusable device designed to be used together with a compatible autoinjector (a single use, needle based, pre-filled injection device for delivery of a drug or biologic into subcutaneous tissue). Figure 1 shows the SmartPilot YpsoMate NS-A2.25 with the paired autoinjector. The SmartPilot YpsoMate NS-A2.25 records device data, injection data and injection process status. The SmartPilot YpsoMate NS-A2.25also provides guidance feedback to the user during the injection.
Note that the SmartPilot YpsoMate NS-A2.25 does not interfere with autoinjector function.

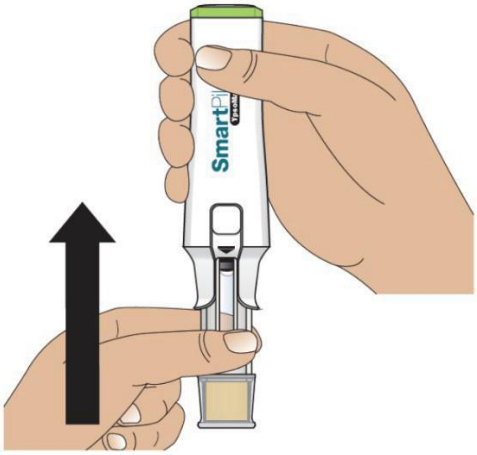

Figure 1*: The autoinjector is inserting into the SmartPilot YpsoMate NS-A2.25*

V. INDICATIONS FOR USE

The SmartPilot YpsoMate NS-A2.25 is indicated for use with the compatible disposable autoinjector to capture and record injection information that provides feedback to the user.

SMARTPILOT MODEL	DRUG MANUFACTURER	DRUG NAME	BRAND NAME
SmartPilot YpsoMate NS-A2.25	Novartis/Sandoz	Secukinumab	Cosentyx

IV. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the predicate device and the subject device are an accessory/ add-on to autoinjectors which guide the user throughout the self-injection process, provide feedback on the completeness of the injection, record data related to the injection, and transfer this data to a companion App.

Also, both the subject device and the predicate device are handheld devices that are intended to be used with compatible injection devices: pre-filled syringes (or pre-filled autoinjectors for the subject device). The subject device has similar dimensions and uses similar materials as the predicate device cleared under K222689. Both the subject device and predicate device feature visual and audible indicators at the start and end of dose to ensure medication is administered correctly. Both the subject and the predicate device provide the same nature of the visual indicators (LEDs for the subject device and the predicate device). Both the subject and the predicate device do not have any drug contact. Both the subject and the predicate device meet requirements for intact skin contact according to ISO 10993-1. Both the subject and the predicate device meet ISO 11608-1 requirements for dose accuracy when evaluated together with their respective compatible devices. Both the subject and the predicate device do not digitally display the dose. Both the subject and the predicate device do not perform any electronically controlled dosing. Both the subject and the predicate device meet IEC 60601-1 requirements for Electrical Safety. Both the subject and the predicate device provide a full dose history displayed on a mobile application. Both the subject and predicate devices Medicine Identification is manually selected by the user during setup and displayed on a mobile application during dosing. For both the subject device and the predicate device the electronic data for dose information is as follows: dose-related data is recorded and dose information is displayed on a mobile application.

Both the subject device and the predicate device have no mechanism to drive a hypodermic needle.

Differences include the use of an inductive sensor in the subject device to monitor injection progress whereas the predicate device uses a motion sensor. While the subject device does not capture dosing information and is only compatible with disposable autoinjectors (patient cannot adjust the dose on the compatible autoinjectors), the subject device is able to record, store and transfer injection data. The subject device is for Rx use, while the predicate device is for OTC use. The user of the subject device inserts autoinjector while for the predicate device, the user attaches Mallya base and button to the compatible disposable insulin pen. While the predicate device meets Cybersecurity Testing requirements and Software V&V per FDA guidances, the subject device additionally meets IEC 62304 requirements and Enhanced Documentation Level. The predicate device is provided together with a mobile application, while the subject device has a mobile application optionally. While the predicate device meets ISO 11608-1 requirements for Dose Accuracy when evaluated with compatible insulin pens, the subject device meets ISO 11608-1 requirements for Dose Accuracy and additionally Activation Force, Injection Time, and Visual / audible feedback when evaluated with compatible YpsoMate AutoInjectors (influence testing with compatible YpsoMateAutoInjectors).

However, since the subject device does not drive the injection process, these minor technological differences do not raise new questions of safety and effectiveness when compared to the predicate device.

To substantiate this evidence-based justification, kindly find the following aspects:

Do the different technological characteristics of the device raise different questions of safety and effectiveness? NO
Per FDA's Guidance The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], "a 'different question of safety or effectiveness' is a question raised by the technological characteristics of the new device that was not applicable to the predicate device and poses a significant safety or effectiveness concern for the new device."

Intended Use: Same in that both devices are intended to detect, record, and transmit injection/dosing information. However, the specific information being detected is partially different than the predicate.

Indications for Use: The product is intended to be used with different combination product brands. Further, the type of combination product is different, autoinjector vs. pre-filled pen injector. This does not raise new or different questions of safety & effectiveness when compared to the predicate device.

Compatible Drugs: The different combination product brands also contain different drugs that address different treatment indications and populations (psoriasis, psoriatic arthritis vs. insulin). However, the differences do not raise new or different questions of safety & effectiveness when compared to the predicate device. This has been fully considered in the provided risk management documentation.

Rx use/OTC: SmartPilot YpsoMate NS-A2.25is intended for prescription use only. This does not raise new or different questions of safety & effectiveness (restricted to HCP professional recommendation) when compared to the predicate device and is incompatible with combination products for which it is not intended.

Functionalities: Different, due to added method of interaction/communication (NFC). This doesn't raise new or different questions of safety & effectiveness when compared to the predicate device. Technology evaluated for safety and effectiveness per same standards/guidance documents. Similar controls required.

Mechanism for capturing information: Different as the SmartPilot YpsoMate NS-A2.25 detects the position of the spring, while the Mallya adapter detects dose dialed through rotational detection mechanism. Methodology is different but intended use is the same. Thus this does not raise new or different questions of safety & effectiveness when compared to the predicate device as the determination of detection accuracy is the same question, with no difference in risk.

Wireless Connectivity: Different, due to added method of interaction/communication (NFC). This doesn't raise new or different questions of safety and effectiveness when compared to the predicate device. Technology evaluated for safety and effectiveness per same standards/guidance documents. Similar controls required.

Data Captured: SmartPilot YpsoMate NS-A2.25 doesn't report the volume of injection but detects the spring position (which indirectly correlates to injection time) to determine and report success and type of injection to the end-user. Mallya also detects dialed dose. This does not raise new or different questions of safety & effectiveness as the difference of fixed dose vs. variable dose is an evaluation of risk. There is comparable risk with determining volume delivered vs the binary determination of injection complete or incomplete. Both are indicators of accuracy.

Data Storage: This is unknown for the predicate and therefore assumed different than the predicate. Does not raise new or different questions of safety & effectiveness as the same question of whether the product stores this information accurately is asked of both products.

Power Source: The SmartPilot YpsoMate NS-A2.25 cannot be recharged but the predicate can. This does not raise new or different questions of safety & sffectiveness, as the questions are the same, can the product adequately perform through the proposed use-life. This has been tested. Even though the product is design and tested for its full lifetime, the product notifies the user adequately by a solid amber light that the battery is low (see section 2.1.1 of the attached file: "Product Description SmartPilot YpsoMate NS-A2.25"). In the case of battery death the SmartPilot does not interfere in the injection function of the YpsoMate, and the YpsoMate injection can be performed safely without any interference by SmartPilot YpsoMate NS-A2.25.

Ypsomed believes that the **SmartPilot YpsoMate NS-A2.25** is substantially equivalent to the predicate device based on the information summarized in the table below:

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th><th>Comparison</th></tr>
<tr><td></td><td>Ypsomed AG

SmartPilot YpsoMate NS-A2.25</td><td>Biocorp Production
K222689
Mallya Injection Pen Adapter (Mallya® for Solostar®)</td><td></td></tr>
<tr><td>Intended Use</td><td>Intended for the capture and recording of injection information.</td><td>Intended for the capture and wireless transmission of dosing information.</td><td>The only difference is that the SmartPilot does not capture dosing information.</td></tr>
<tr><td>ProCode / Reg #</td><td>QOG / 21 CFR 880.5860</td><td>QOG / 21 CFR 880.5860</td><td>Same</td></tr>
<tr><td>Class / Reg Pathway</td><td>Class II / 510(k)</td><td>Class II / 510(k)</td><td>Same</td></tr>
<tr><td>Indications for Use</td><td>The SmartPilot YpsoMate NS-A2.25 is indicated for the capture and recording of injection data from the compatible disposable autoinjector. The following autoinjector is compatible:

<table><tr><th>SMARTPILOT MODEL</th><th>DRUG MANUFACTURER</th><th>DRUG NAME</th><th>BRAND NAME</th></tr><tr><td>SmartPilot YpsoMate NS-A2.25</td><td>Novartis/ Sandoz</td><td>Secukinumab</td><td>Cosentyx</td></tr></table></td><td>The Mallya Injection Pen Adapter is indicated for the capture and wireless transmission of dosing information from compatible reusable and disposable pen injectors. The following Injection pens are compatible.

<table><tr><th>Mallya model</th><th>Insulin brand Name</th><th>Molecule Name</th><th>Molecule Concentration</th></tr><tr><td rowspan="5">Mallya designed for Solostar® SANOFI injection pen</td><td>Lantus</td><td>GLARGINE</td><td>100 IU/mL</td></tr><tr><td>Toujeo</td><td></td><td>300 IU/mL</td></tr><tr><td>Admelog</td><td>LISPRO</td><td>100 IU/mL</td></tr><tr><td>Apidra</td><td>GLULISINE</td><td>100 IU/mL</td></tr><tr><td>Soliqua 100/33</td><td>GLARGINE AND LIXISENATIDE</td><td>100 IU/mL +33 mcg/mL</td></tr></table></td><td>Different:
- The SmartPilot does not capture or record dosing information itself, the dose is static with compatible YpsoMate Autoinjectors at 2.25ml
- The SmartPilot does record Injection Data (Date, Time, Injection Outcome), Device Data
- The SmartPilot is only compatible with disposable autoinjectors</td></tr>
<tr><td>Compatible Drugs</td><td>FDA approved drugs in YpsoMate Autoinjectors.</td><td>FDA approved SoloStar® insulin injection pens.</td><td>Different: both devices are compatible with FDA approved autoinjectors or injection pens.</td></tr>
<tr><td>Preparation for Injection</td><td>User inserts YpsoMate Autoinjector</td><td>User attaches Mallya base and button to disposable insulin pen</td><td>Different: user inserts autoinjector or pen respectively. For SmartPilot the user only needs to insert the compatible YpsoMate Autoinjector.</td></tr>
<tr><td>Drug Contact</td><td>None</td><td>None</td><td>Same</td></tr>
<tr><td>Biocompatibility defined by ISO 10993-1</td><td>Meets requirements for intact skin contact</td><td>Meets requirements for intact skin contact</td><td>Same</td></tr>
</table>

	Subject Device	Predicate Device	Comparison
	Ypsomed AG SmartPilot YpsoMate NS-A2.25	Biocorp Production K222689 Mallya Injection Pen Adapter (Mallya® for Solostar®)	
Activation Force	Meets ISO 11608-1 requirements when evaluated with compatible YpsoMate AutoInjectors	None	Different: Similar, additional EPRs of YpsoMate Autoinjectors reflected
Dose accuracy	Meets ISO 11608-1 requirements when evaluated with compatible YpsoMate AutoInjectors	Meets ISO 11608-1 requirements when evaluated with compatible pens	Same
Injection Time	Meets ISO 11608-1 requirements when evaluated with compatible YpsoMate AutoInjectors	None	Different: additional EPRs of YpsoMate Autoinjectors reflected
Visual / audible feedback	Meets ISO 11608-1 requirements when evaluated with compatible YpsoMate AutoInjectors	None	Different: additional EPRs of YpsoMate Autoinjectors reflected
Digital Dose Display	No	No	Same
Electronically Controlled Dosing	No	No	Same
Disposable/Reusable	Reusable	Reusable	Same
Single Patient Use	Yes	Yes	Same
Rx use / OTC	Rx use	OTC	Different: Rx use for SmartPilot does not raise different questions of safety and effectiveness.
Functionalities	• Guides the patient through the injection procedure • Records date and time, and injection result • Data transfer possible to paired App and Cloud via the SDK	• Guides the patient through the injection procedure • Captures dosing information, date and time of injection • Wireless transmission of injection data to paired App	Different: the SmartPilot does not record dosing information since the patient cannot adjust the dose on the compatible autoinjectors.
Mechanism for capturing information	Sensor senses the position of the spring inside the YpsoMate Autoinjector	Sensor senses dose dialed through rotation of dosing mechanism during dose setting	Different: mechanical sensor.
Control or Impact Drug Delivery	No	No	Same
Fluid Pathway Contact	No	No	Same
User Feedback During Injection Process	Visual (LEDs) and audible (beeps)	Visual (LEDs) and audible (beeps)	Same
Electrical Safety	Meets IEC 60601-1 requirements	Meets IEC 60601-1 requirements	Same

	Subject Device	Predicate Device	Comparison
	Ypsomed AG SmartPilot YpsoMate NS-A2.25	Biocorp Production K222689 Mallya Injection Pen Adapter (Mallya® for Solostar®)	
Embedded Firmware	Meets IEC 62304 requirements; Enhanced Documentation Level, Cybersecurity Testing and Software V&V per FDA guidances	Cybersecurity Testing and Software V&V.per FDA guidances	Different: SmartPilot also meets the IEC 62304 requirements and Enhanced Documentation Level
Wireless Connectivity	Bluetooth Low Energy (BLE) and Near Field Communication (NFC)	Bluetooth Low Energy (BLE)	Different: SmartPilot also includes NFC capability.
Data Captured	Time and date of injection Result of injection (complete or incomplete)	Time and date of injection Dialed dose Differentiates prime vs dose	Different: the SmartPilot does not capture dialed dose.
Data Storage	Up to 120 injections	Unknown	Different
Dose History	Full: Displayed on mobile application, if user chooses to use mobile application	Full: Displayed on mobile application	Different: Similar, for SmartPilot, the mobile app is optional.
Electronic Data for Medicine Identification	Medicine Identification manually selected by user during setup. If user chooses to use mobile app, medicine identification displayed on mobile application during dosing.	Medicine Identification manually selected by user during setup and displayed on mobile application during dosing	Different: for SmartPilot, the mobile app is optional.
Electronic Data for Dose Information Capture	Dose-related data recorded; dose information displayed on mobile application	Dose-related data recorded; dose information displayed on mobile application	Same
Energy Source	Electrical	Electrical	Same
Power Source	Non-replaceable batteries that cannot be recharged by the user	Non-replaceable, rechargeable Li-ion battery	Different: both devices operate with non-replaceable batteries.
Lifetime	2 years of use	2 years of use	Same
Shelf Life	3 years	2 years	Different: SmartPilot has a ShelfLife of 3 years.

V. PERFORMANCE DATA

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

1.1.1 Biocompatibility testing

The biocompatibility evaluation for the SmartPilot YpsoMate NS-A2.25 was conducted in accordance with

- The FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995
- ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,"
  - Testing included the Cytotoxicity according to ISO 10993-5, Ed.32009-06-01
  - Testing included the Sensitization according to ISO 10993-10, Ed.4 2021-11
  - Testing included the Irritation according to ISO 10993-23, Ed.1 2021-01

The injection data capture device is considered tissue contacting for a duration until 30 days.

1.1.2 Compatibility Testing with YpsoMate 2.25ml

Influence Testing has been performed with the intention to prove that the SmartPilot YpsoMate NS-A2.25 does not have a negative impact on the Essential Performance Requirements (EPRs) of the compatible YpsoMate 2.25ml autoinjector. This influence testing has been based on ISO 11608-1:2022 and ISO 11608- 5:2022 standards.

1.1.3 Basic safety and electromagnetic compatibility (EMC)

Basic safety and EMC testing were conducted on the SmartPilot YpsoMate NS-A2.25, The device complies with the IEC 60601-1, Ed.3.2 2020-08 and IEC 60601-1-11, Ed.2.1 2020-07 standards for safety and the IEC 60601-1-2:2014 incl. AMD 1:2021 standard for EMC. It also complies with IEC 62133-2:2017 + A1:2021.

1.1.4 Wireless communication testing

Wireless communication testing has been performed according to the following standards:

- FCC 47 CFR Part 15B
- FCC 47 CFR Part 15.225
- FCC 47 CFR Part 15.247

Wireless coexistence testing has been performed according to the following standards:

- IEEE ANSI USEMCSC C63.27-2021
- AIM 7351731:2021

1.1.5 Software Verification and Validation Testing

- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, Guidance for industry and FDA Staff; Content of Premarket Submissions for Device Software Functions, June 14 2023". The software for this device was considered as a documentation level "enhanced", since a failure or latent flaw in the software could result in serious injury to the patient/operator.
  - Based on ANSI AAMI ISO 62304:2006/A1:2016 and its requirements
  - Software Verification and Validation per FDA Guidelines
  - Including Cybersecurity Testing
  - Interoperability testing per FDA guidance

1.1.6 Electrical Hardware Requirements Testing

- Power and Battery Requirements
  Battery type and compliance with standards (IEC 60086-4, IEC 62133), Storage lifetime and usage lifetime specifications., Prevention of overcharging, Power management and monitoring (e.g., activation and detection switches).
- Functional Requirements
  BLE Bluetooth® transceiver functionality, NFC tag functionality (passive compliance, data configuration, detection when read), Inductance measurement for sensor coils.
  Electromechanical switches for device detection and power activation, Motion detection and thresholds, Temperature measurement of electronics.
- Indicator and Feedback Systems
  Visual indicators with specific wavelength and intensity requirements (red, green, blue), Brightness control for visual indicators (0%–100%), Acoustic user feedback with adjustable sound volume (0%–100%).
- Interfaces and Diagnostics
  Programming and diagnostics interface, Serial communication via UART, Secure activation method requiring physical access.
- Durability and Lifetime
  Switching cycles for electromechanical components (e.g., detection switches), Device lifetime specifications (e.g., 3-year storage, 2-year or 120-use operational lifespan), Operational tolerances (temperature, pressure, humidity).

1.1.7 Mechanical Testing

- Use Force Testing
- Weight, Locking Flag Visibility
- Insertion of YpsoMate 90°rotated
- Axial Load on inserted YpsoMate
- Twisting of inserted YpsoMate
- Lifetime testing

1.1.8 Software Verification & Validation

- Based on ANSI AAMI ISO 62304:2006/A1:2016 software classification B
- Software Verification & Validation per FDA guidance
- Cybersecurity Verification & per FDA guidance
- Interoperability testing per FDA guidance

1.1.9 Lifetime and Shelf Life Testing and Functional Stability Testing

- Accelerated lifetime testing of battery power supply
- Storage lifetime testing (shelf life) of primary battery
- Accelerated Aging testing for lifetime and the functional check after accelerated aging.
- Mechanical and Electronics lifetime testing for claimed 120 injections over the course of the device lifetime.

1.1.10 Human Factors

- Human Factors testing per FDA guidance
- Human Factors testing has been performed according to the following standard:

- IEC 60601-1-6:2010/AMD2:2020.
- Formative and Summative Usability Evaluations

1.1.11 Transportation Testing

- Transportation testing has been performed according to the following standard:
  - ASTM D4169-22 “Standard Practice for Performance Testing of Shipping Containers and Systems”

1.1.12 Standards Overview

Standard	Version	Title
Biocompatibility		
ISO 10993-1	2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 10993-2	2022	Biological Evaluation of medical devices – Part 2: Animal welfare requirements
ISO 10993-5	2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
ISO 10993-12	2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 10993-18	2020/AMD1 20222	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
ISO 10993-23	2021	Biological evaluation of medical devices – Part 23: Tests for irritation
Basic Safety and EMC		
IEC 60601-1, Ed. 3.2	2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-11	2020	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 62133-2	2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications – Part 2: Lithium Systems
Software & Cybersecurity		
IEC 62304	2006 + AMD 1 2016	Medical device software. Software Life Cycle Processes
IEC 81001-5-1	Ed.1.0, 2021	Health software and health IT systems safety effectiveness and security – Part 5-1; Security – Activities in the product life cycle
ANSI AAMI SW96	2023	Standard for medical device security – Security risk management for device manufacturers
Wireless		
AIM 7351731	2021	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
IEEE ANSI USEMCSC C63.27	2021	American National Standard for Evaluation of Wireless Coexistence
Usability		
IEC 60601-1-6	2020	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
ANSI AAMI IEC	2015 + AMD1	Medical devices Part 1: Application of usability engineering to medical devices including

62366-1	2020	Amendment 1
Transportation		
ASTM D4169-22	2022	Standard Practice for Performance Testing of Shipping Containers and Systems
Accelerated Aging		
ASTM F1981-21	2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices

Summary

Based on the performance data as documented in the tests listed above, the SmartPilot YpsoMate NS-A2.25 was found to be as safe and as effective as the predicate device.

VI. CONCLUSIONS

The non-clinical data supports the safety of the device and the verification and validation activities demonstrate that the SmartPilot YpsoMate NS-A2.25 should perform as intended in the specified use conditions.

The data presented supports that the SmartPilot YpsoMate NS-A2.25 is substantially equivalent to the predicate device for specific indications and technological characteristics of the predicate device with regards to data recording and transmission.