July 18, 2025

Takeda Pharmaceuticals
Avanti Sawant
Associate Director Global Regulatory Affairs, Device PDT
500 Kendall Street
Cambridge, Massachusetts 02142

Re: K243404
Trade/Device Name: HyHub™ and HyHub™ Duo Vial Access Devices
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LHI
Dated: June 20, 2025
Received: June 20, 2025

Dear Avanti Sawant:

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,

David Wolloscheck -S

David Wolloscheck, Ph.D.
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)*
K243404

Device Name
HyHub™ and HyHub™ Duo Vial Access Device

Indications for Use *(Describe)*
HyHub™ and HyHub™ Duo vial access devices are indicated for patients 17 years of age or older to allow a drug to be transferred from vials without using a needle, as prescribed, in a home environment or clinical setting.

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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K243404 – 510(K) SUMMARY

DATE SUBMITTED

18 Jul 2025

Submitter

Takeda Pharmaceuticals U.S.A.,
Inc. 500 Kendall Street
Cambridge, MA 02142

Contact

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617-943-1107

Device Information

Trade name: HyHub™ and HyHub™ DUO Vial Access Devices
Configurations: Vial Access Device with 2 docking stations
Vial Access Device with 4 docking stations
Common Name: I.V. Fluid Transfer Set
Classification Regulation: 880.5440
Classification Name: Intravascular administration set
Device Classification: Class II
Product Code: LHI

Predicate Device

Trade Name: Fleboset MULTIPLE
510K#: K040456
Product Code: LHI
Manufacturer: LABORATORIOS GRIFOLS, S.A.

Device Description Summary

The HyHub™ and HyHub™ DUO vial access devices (VAD) are a stand-alone, single-use, disposable, non-pyrogenic, gamma sterilized device, which are intended to support the infusion of two medicinal liquids, as prescribed, in a home environment or clinical setting. The VAD is designed to accommodate up to two (2) or four (4) dual vial units (DVU) to be docked onto the VAD infusion tray which allows the transfer of medicinal liquids in a sequential, needleless manner using standard connections for syringes, applicable pumps, and infusion sets.

Environment of Use

The HyHub™ and HyHub™ DUO vial access devices are used in clinical and home environments.

Indications for Use

HyHub™ and HyHub™ DUO vial access devices are indicated for patients 17 years of age or older to allow a drug to be transferred from vials without using a needle, as prescribed, in a home environment or clinical setting.

Summary of Technological Characteristics

The following technological characteristic of the HyHub™ and HyHub™ DUO vial access devices are substantially equivalent to those of the Predicate, Fleboset MULTIPLE:

- Use of a spike to pierce vials and withdraw drug product(s).
- Multiple spikes connected in series with flexible tubing segments.
- Spike “vent” function facilitated by hydrophobic air filter allowing for withdrawal from vial without having to inject air.
- Enables continuous delivery of drug product(s) from multiple source containers.
- Can be used in conjunction with an infusion pump.

Summary of Comparison with Predicate Device

Characteristics	HyHub™ and HyHub™ DUO Vial Access Device	Fleboset Multiple	Comparison
Indications for Use	HyHub™ and HyHub™ DUO vial access devices are indicated for patients 17 years of age or older to allow a drug to be transferred from vials without using a needle, as prescribed, in a home environment or clinical setting.	Fleboset Multiple is an ancillary device used as fluid pathway through which substances from six glass source flasks containing the same solution may be continuously delivered for I.V. administration when used in conjunction with a gravity or pump infusion set to channel the solution from the source containers to the infusion set.	Same
Sterilization Method	Gamma Radiation Validation per ISO-11137	Ethylene Oxide Validation per ISO-11135	Different
Discussion: Both predicate and subject devices were validated to the sterility assurance levels of 10^{-6}. The results demonstrated that the differences do not raise any new questions of safety and effectiveness for the subject device.			
Spike	Yes	Yes	Same
Fluid Path	Two	One	Different
Discussion: The predicate device contains six (6) spikes connected in series with flexible tubing segments, made up of Polyvinyl Chloride (PVC). Similarly, the subject device has two separate fluid paths which contain spikes connected in series with tubing segments, made of PVC (non-DEHP). The subject device fluid paths have undergone flow testing, residual volume testing and biocompatibility testing to support the intended use. The results demonstrated that the differences do not raise any new questions of safety and effectiveness for the subject device.			
Hydrophobic Air Filter	Yes	Yes	Same
Single use	Yes	Yes	Same
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Same
Source Containers	Up to 2 (HyHub DUO) Up to 4 (HyHub)	Up to 6	Different
Discussion: The predicate device allows withdrawal of drug product from six (6) source containers simultaneously. The subject device allows withdrawal of the drug product from up to two (2) or four (4) source containers simultaneously. Both predicate and subject device can be connected to an infusion pump. Pump compatibility with the VAD was assessed via flow testing and residual volume testing to support the intended use. The results demonstrated that the differences do not raise any new questions of safety and effectiveness for the subject device.			

Performance Bench Testing Summary

The following bench tests were performed in accordance with applicable FDA-recognized standards or internally validated protocols guided by a risk management process:

- Leak test
- Particulate test
- Luer connectors compatibility
- Stopper fragmentation test
- Sterile packaging test
- Flow test
- Residual/Injectable Volume test
- Human Factors Validation

Biocompatibility Testing Summary

Biocompatibility evaluation was conducted in accordance with ISO 10993-1, considering the device's classification (externally communicating, blood path indirect, with prolonged exposure duration (>24 h to 30 d)). The following endpoints were assessed:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Material mediated pyrogenicity
- Acute systemic toxicity
- Subacute Toxicity (Dual Route Repeated Exposure)
- Hemolysis test
- Chemical Characterization
- Drug Compatibility

Conclusions

Based upon the comparison of the labeling, the technological and functional characteristics, the information provided in this submission – including results from risk assessments and testing activities related to verification, validation, performance, and usability/human factors – demonstrates that the VAD device functions as intended and is substantially equivalent to the predicate device. Therefore, Takeda concludes that the subject device, VAD, is substantially equivalent to the predicate device (K040456).