August 17, 2018

J & J Solutions, Inc. d/b/a/ Corvida Medical
Dana Schramm
Chief Operating Officer
2945 Lone Oak Drive, Suite 150
Eagan, Minnesota 55121

Re: K180574
Trade/Device Name: Halo System
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: ONB
Dated: July 2, 2018
Received: July 9, 2018

Dear Dana Schramm:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180574

Device Name
Halo®

Indications for Use *(Describe)*
The Halo® system is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The Halo® system also prevents microbial ingress for up to 7 days.

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
K180574

SUBMITTER

J & J Solutions, Inc. d/b/a Corvida Medical
2945 Lone Oak Drive, Suite 150
Eagan, Minnesota 55121

ESTABLISHMENT REGISTRATION NUMBER

3012235045

CONTACT

Dana Schramm
Chief Operating Officer
Ph. 319-335-2547 x103
Fax. 319-250-4135
dana.schramm@corvidamedical.com

DATE PREPARED

August 8, 2018

NAME OF MEDICAL DEVICE

Trade Name:	Halo®
Common/Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
Classification Name:	Intravenous Administration Set

DEVICE CLASSIFICATION

Classification Panel:	General Hospital
Regulatory Class:	II
Product Code:	ONB
Regulation Number:	21 CFR 880.5440

MANUFACTURER

Corvida Medical
2945 Lone Oak Drive, Suite 150
Eagan, Minnesota 55121

PREDICATE DEVICE

Trade Name:	Halo® (K150486)
Common/Usual Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System
Classification Name:	Intravenous Administration Set

DEVICE DESCRIPTION

The Halo® is a Closed System Transfer Device (CSTD) for the safe handling of hazardous drugs, especially for the compounding and administering of hazardous drugs according to the National Institute for Occupational Safety and Health (NIOSH) definition of an airtight and leak proof closed system transfer device. It is a sterile single-use device. There are five components of the Halo® system, Closed Vial Adaptor (CVA), Closed Syringe Adaptor (CSA), Closed Bag Adaptor (CBA), Closed Line Adaptor (CLA), and Closed Vial Converter (CVC). These components integrate with industry standard luer-lock syringes, IV bags, infusion sets, and other patient connections to form a complete closed system. This system prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols, and spills. In addition, the components are designed to prevent microbial ingress into the system, including maintaining sterility of drugs in the vial for up to 7 days. The ability to prevent microbial ingress for up to 7 days should not be interpreted as modifying, extending, or superseding a manufacturer labeling recommendations for the storage and expiration dating. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information.

The system uses industry compatible luer locks, bag spikes and spike ports, dual lumen spikes, single lumen needles, and dry to dry compression fit seals when connecting Halo® components together. A single lumen needle perforates the dry-to-dry compression fit seals for the transfer of drugs between Halo® components. Upon separation the needle is retracted and the seal membrane prevents transfer of environmental contaminants into the system and/or escape of drug or vapor.

INDICATION FOR USE

The Halo® system is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The Halo® system also prevents microbial ingress for up to 7 days.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES

Equivalence was determined using a side by side tabular comparison between the predicate and proposed devices which included: Features, Intended Use, Labeling, Materials, Specifications, Performance Data, and Technological Aspects. The proposed modified device is substantially equivalent to the predicate device and does not raise

different questions of safety or effectiveness.

Regulatory Classification, Risk, and Indications for Use

	Proposed Device (K180574)	**Predicate Device (K150486*)***
Indications for Use	The system is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The Halo® system also prevents microbial ingress for up to 7 days.	The system is an airtight and leak proof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor concentrations outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The Halo® system also prevents microbial ingress for up to 168 hours.
Classification	Class II	Class II
Regulation Number	888.5440	888.5440
Product Code	ONB	ONB

No differences in Regulatory Classification, Risk, or Indications for Use except for the conversion of 168 hours to 7 days for microbial ingress prevention claim.

Technological Characteristics

	Proposed Device (K180574)	**Predicate Device (K150486*)***
System Components	13mm Vial Adaptor (CVA130)	13mm Vial Adaptor (CVA130)
	20mm Vial Adaptor (CVA200)	20mm Vial Adaptor (CVA200)
	28mm Vial Adaptor (CVA280)	28mm Vial Adaptor (CVA280)
	Closed Syringe Adaptor (CSA100)	Closed Syringe Adaptor (CSA100)
	Closed Bag Adaptor (CBA100)	Closed Bag Adaptor (CBA100)
	Closed Line Adaptor (CLA100)	Closed Line Adaptor (CLA100)
	Closed Line Adaptor (CLA200G)	NA
	Closed Line Adaptor (CLA200B)	NA
	Closed Vial Converter (CVC130)	NA

Characteristics	Closed System used to reconstitute, transfer, and administer antineoplastic and other hazardous drugs in healthcare setting. Indicated to reduce exposure of healthcare personnel and the surrounding environment to chemotherapy agents.	Closed System used to reconstitute, transfer, and administer antineoplastic and other hazardous drugs in healthcare setting. Indicated to reduce exposure of healthcare personnel and the surrounding environment to chemotherapy agents.
Principles of Operation	Multi-components intended to be used as a system.	Multi-components intended to be used as a system.
Technological Characteristics	The proposed system consists of four main components that attach to standard drug vials, syringes, patient lines or secondary sets, and standard IV bags.	The predicate system consists of four main components that attach to standard drug vials, syringes, patient lines or secondary sets, and standard IV bags.
	The proposed CSTD system uses industry compatible luer lock, spike, and needle safe connections to form the closed systems for drug transfer.	The predicate CSTD system uses industry compatible luer lock, spike, and needle safe connections to form the closed systems for drug transfer.
	The proposed CSTD system uses polymer seals that prevent environmental contaminants from entering into the system and/or escape of drug or vapor. When system components are joined together the seals are pressed together and then pierced by needles. When disconnected, the polymer reseals to create a leak-proof and drug residual-free connection.	The proposed CSTD system uses polymer seals that prevent environmental contaminants from entering into the system and/or escape of drug or vapor. When system components are joined together the seals are pressed together and then pierced by needles. When disconnected, the polymer reseals to create a leak-proof and drug residual-free connection.
Device Type	Rx/Single Use	Rx/Single Use
Target Users	Licensed Pharmacists/Health Care Professionals	Licensed Pharmacists/Health Care Professionals
Environment	Hospitals and clinics	Hospitals and clinics
Sterilization	EtO / SAL 10^{-6}	EtO / SAL 10^{-6}

No differences in technological characteristics, system function, user populations, use environment, or sterilization method.

Discussion of Design/Manufacturing Differences

Changed Component	Change Description	Change Discussion on SE
Closed Line Adaptor (CLA)	Material - Polyethylene to Polypropylene	Changed component material to take advantage of molding and assembly productivity. Polypropylene's use in medical devices and CSTD's is well documented. This material change has been fully tested for liquid escape, vapor escape, and biocompatibility. No different questions of safety or effectiveness are raised.
	Components – Added Locking Line Adaptors • CLA200G • CLA200B	The CLA200 models incorporate a locking clip to provide added retention to a patient's line. All other dimensions are the same as the existing predicate CLA. No different questions of safety or effectiveness are raised.
	Assembly • CLA100 • CLA200G • CLA200B	The luer lock threads are now created by an injection molded insert that is ultrasonically welded into the body. The predicate device consisted of a single piece injection molded body with luer lock threads. No different questions of safety or effectiveness are raised.
Closed Syringe Adaptor (CSA)	Assembly	To take advantage of productivity and manufacturing economies, changed CSA needle bond from injection over mold to UV curable adhesive. This design and manufacturing change has been tested for liquid escape, vapor escape, and adhesive bond tensile and compression strength. No different questions of safety or effectiveness are raised. All other features and dimension remain the same as the existing predicate CSA.
13mm Vial Converter (CVC130)	Component Addition	Added 13mm Vial Converter as an accessory component that enables the use of the 20mm Closed Vial Adaptor with a 13mm capped vial. Test results establish that the CVC130 connection performs in a similar fashion to the reference devices (CVA130 and CVA200). Assemblies were tested for liquid escape, vapor escape, attachment and detachment force. No different questions of safety or effectiveness are raised.
Labeling	Labels and IFU's	Added labels and directions for the new components. No different questions of safety or effectiveness are raised.

SUMMARY OF PERFORMANCE TESTING

Results from tests completed on the Halo® components demonstrate it to be an easy to use device that prevents microbial ingress and/or escape of drug or vapor through multiple reconnections of components up to 14 times and are substantially equivalent with respect to operational performance. Product testing consisted of the following:

Product Functional Testing	Results
• Fluorescein Leak Test	No Leaks
• Alcohol Vapor Leak Test	No Leaks
• Pressure Test	No Leaks
• Insertion (Connection) and Retention Force	Pass
• ISO594-1 Part 1: General Requirements	Pass
• ISO 594-2 Part 2: Lock Fittings	Pass
• ISO 8536-4 Infusion equipment for medical use: Part 4	Pass

Package Integrity and Shelf Life

Packaging and Shelf Life validation was performed on aged Halo® packaging according to ASTM F2096: Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization, ASTM F1886: Standard Test Method for Determining Integrity of Seals for Medical Device Packaging by Visual Inspection, and ASTM F88 standard test method for seal strength of flexible barrier materials. All testing passed.

Biocompatibility

Biocompatibility testing was performed on the Halo® materials according to FDA Guidance and ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included cytotoxicity, sensitization, irritation, systemic toxicity, and hemocompatibility according to standards set forth in ISO 10993- 4, Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood, ISO 10993- 5, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization, and ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity. All testing passed. A chemical characterization and toxicological risk assessment was used to evaluate the subchronic systemic toxicity endpoint (see Extractables Screening section below).

Sterility

Sterilization validation was performed on the finished Halo® components according to ISO 11135 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices. Testing included pyrogenicity, bioburden, and EO residuals to standards set forth in ISO 10993-7 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals, ISO 11737-1 Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products, and AAMI/ANSI ST72 bacterial endotoxins - test methods, routine monitoring, and alternatives to batch testing. All testing passed.

DMA Compatibility

Compatibility testing was performed to validate Halo® compatibility with antineoplastic drugs and DMA (N,N-dimethylacetamid).
Halo® was found to be compatible.

Extractables Screening

Extractables screening was completed to determine what compounds and their estimated concentrations are extracted from the Halo® Closed System Transfer Device for hazardous drugs (CSTD) under the conditions of the extractions (72 hours at 37°C) when extracted in the following solvents: hexane, 50% ethanol, pH 3 (HCl adjusted) 0.9% saline, and 33% aqueous dimethylacetamide (DMA). A toxicological risk assessment was performed on the extracted compounds.

Microbial Ingress Protection

Microbial ingress testing was performed on Halo® to validate microbial ingress protection after repetitive needle penetration of the seal. These test results were originally reported in K150486. Testing results demonstrate Halo® was protected against microbial ingress for a period of 7 days after breaching the seal 14 times with the CSA needle. All sealing features remain the same as the predicate devices and the design changes do not modify any of the sealing properties from the original predicate devices. The ability to prevent microbial ingress for up to 7 days should not be interpreted as modifying, extending, or superseding a manufacturer labeling recommendations for the storage and expiration dating. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information.

Particulate Testing

Particulate contamination testing was performed on the Halo® system according to USP 788 to demonstrate lack of contamination. Testing results demonstrated particulate levels in the Halo system are low and meet USP 788 requirements.

Substantial Equivalence Conclusion

Performance testing established that the proposed Halo® devices performed substantially equivalent (SE) to the performance testing on the predicate Halo® devices. Equivalence was determined using a side by side tabular comparison between the predicate and proposed Features, Intended Use, Labeling, Materials, Specifications, Performance Data, and Technological Aspects. The proposed devices are Substantially Equivalent to the predicate devices.

Based on the analysis of the comparison between the predicate and proposed devices regarding risk analysis, design controls, and performance evaluation the data shows the modifications do not raise different questions of safety or efficacy and demonstrates substantial equivalence to the predicate device.