DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 24, 2015

J & J Solutions, Inc. d/b/a/Corvida Medical
Mr. Dana Schramm
Vice President of Manufacturing/Operations
2261 Crosspark Road, Suite 127
Coralville, IA 52241

Re: K150486
Trade/Device Name: Halo ™
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: ONB
Dated: June 12, 2015
Received: June 17, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
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: January 31, 2017
See *PRA Statement below.*

51O(k) Number *(if known)*

K150486

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 168 hours.

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 – K150486

SUBMITTER:

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DATE PREPARED:

July 23, 2015

NAME OF MEDICAL DEVICE:

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

DEVICE CLASSIFICATION:

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

MANUFACTURER:

Corvida Medical

2261 Crosspark Road, Suite 127

Coralville, Iowa 52241

PREDICATE DEVICES:

Proprietary Name:	BD PhaSeal CSTD (K123213, K130197, K140591)
Common/Usual Name:	Closed System Transfer Device
Classification Name:	Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System

DEVICE DESCRIPTION:

The Halo™ is a Closed System Transfer Device (CSTD) for the 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 four components of the Halo™ system, Closed Vial Adaptor (CVA), Closed Syringe Adaptor (CSA), Closed Bag Adaptor (CBA) and Closed Line Adaptor (CLA). 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 168 hours. The ability to prevent microbial ingress for 168 hours should not be interpreted as modifying, extending, or superseding a drug manufacturers labeling recommendations for the storage and expiration dating. Refer to drug manufacturer's recommendations 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.

INTENDED USE / INDICATION FOR USE:

Halo™	BD PhaSeal (Predicate) from K140591
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 168 hours.	The PhaSeal system is an airtight and leakproof 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 PhaSeal system also prevents microbial ingress.

The Intended Use / Indication for Use statements are identical except for the inclusion of "for up to 168 hours" at the end of the Halo™ statement. This was included based on the microbial ingress testing performed on the Halo system.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES

Technologically, the Halo™ system is similar to the predicates in terms of design and performance. The predicate system consists of four main components that attach to standard drug vials, syringes, patient lines or secondary sets, and standard IV bags. Both the subject and predicate CSTD systems use industry compatible luer lock, spike, and needle safe connections to form the closed systems for drug transfer. Both systems have seals that prevent environmental contaminants from entering into the system and/or escape of drug or vapor. Comparative testing against the predicate device confirmed there were no new questions raised regarding safety or efficacy of the Halo™ device.

Differences between the Halo™ and the predicate CSTD exist in the following:

- The Halo™ Closed Syringe Adaptor and mating components connections are made utilizing a push-on, pull-off coupling action to engage seals where the predicate injector employees a push and twist together connection.

The push-on, pull-off connection was validated through performance testing completed on the Halo™ and predicate devices establishing substantial equivalence with respect to operational performance. This comparative testing against the predicate device confirmed there were no new questions raised regarding safety and effectiveness of the Halo™ device.

SUMMARY OF PERFORMANCE TESTING

Results from tests completed on the Halo™ components demonstrates that the system 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. Testing consisted of the following:

- Fluorescein Test
- System Pressure Test
- Vapor Test
- Closed Bag Adapter (CBA) Leakage
- Closed Line Adapter (CLA) Pressure Test
- Closed Vial Adaptor (CVA) Insertion and Retention Force
- Closed Syringe Adaptor (CSA) Connection Force
- CLA and CBA Residual Volume
- Human Factors / Comparative testing
- Packaging testing
- ISO594 Luer Fitting Compliance Test
- CBA Spike Port Insertion and Retention Force (IV set)
- Particulate Contamination
- CBA Insertion and Retention Force (IV bag)
- Microbial Ingress Testing
- Comparative testing against the predicate
- Extended Beyond-use-date drug vial sterility testing
- Chemical Tests
- Extractables/Leachables Testing

The Halo™ was tested for biocompatibility per ISO 10993-1, tests included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility and pyrogenicity.

SUBSTANTIAL EQUIVALENCE

Based on the information contained in this submission, it is concluded that the Halo™ is substantially equivalent to the identified predicate devices already in interstate commerce within the USA.

CONCLUSIONS

Equivalence for the Halo™ is based on similarities in indications for use, design features, materials, operational principals, and technological characteristics as compared to the predicate devices. Results of performance testing for the Halo™ system demonstrates the device is as safe, as effective, and performs as well as the predicate devices.