



Food and Drug Administration
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December 4, 2015

KIRO Robotics S.L.
c/o Ms. Korina Akhondzadeh
KARA & Associates
6965 El Camino Real, Suite 105-428
Carlsbad, CA 92009

Re: K152441
Trade/Device Name: KIRO Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI, NEP
Dated: October 30, 2015
Received: November 2, 2015

Dear Ms. Akhondzadeh:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

 Tina Kiang -
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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

Indications for Use

510(k) Number (if known)

K152441

Device Name

KIRO Set

Indications for Use (Describe)

The KIRO Set is a sterile, single-use disposable ancillary device used with the peristaltic pumps in the KIRO Oncology pharmacy compounding device for the transfer of fluids into sterile powder drug vials for reconstitution of intravenous drugs or into sterile medication containers for intravenous drug administration.

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

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

KIRO Robotics S.L.
Polo de Innovación Garaia
Goiru Kalea 1, Edificio B, Planta 2
C.P. 20500 Mondragon Gipuzkoa
SPAIN

Phone: +34 943-252-249
Contact at KIRO Robotics: Naiara Telleria

Official Correspondent

Korina A. Akhondzadeh
KARA & Associates - Regulatory Consultant to KIRO Robotics
6965 El Camino Real, Suite 105-428
Carlsbad, CA 92009
Phone: 760-798-9642
Fax: 760-798-9643

Date Prepared: August 25, 2015

II. DEVICE

Device Name:	KIRO Set
Common/Usual Name:	Set, I.V. Fluid Transfer
Classification Name:	Intravascular administration set (21 CFR 880.5440)
Product Code:	LHI
Secondary Product Code:	NEP
Class:	II

III. PREDICATE DEVICE

Predicate Device

Sets Gri-Fill 3.0, K050339

This predicate device has not been subject to a recall.

Reference Device

Baxa Tubing Set (for Pharmacy Pump), K872743

This reference device has not been subject to a recall.

IV. DEVICE DESCRIPTION

The KIRO Set is a disposable sterile, single-use fluid transfer tubing set medical device that when placed in one of the double channel peristaltic pumps integrated in the KIRO Oncology pharmacy compounding device, the KIRO Set allows the accurate and fast transfer of sterile fluids from a large source container into a drug vial for the reconstitution of lyophilized drugs (powder), or into a final medication container from which an intravenous medication will be administered. Sterile fluids delivered can be saline (0.9% sodium chloride), 5% glucose, Water for Injection (WFI) or any aqueous diluent which is adequate for the dilution of drugs into the right concentration for intravenous administration.

The KIRO Set is comprised of medical grade silicone tubing with a central double tubing channel pathway for use in the KIRO Oncology peristaltic pump. The KIRO Set includes a filtered vented bag spike for connection to source containers on one end and a male luer lock connector on the outlet end for connection to a dosing spike to allow for dosing into vials for reconstitution or direct connection to final medication containers such as infusion bags, cassettes or elastomeric pump reservoirs.

The device is intended to be used inside the KIRO Oncology compounding area, which is an ISO5 environment for the compounding of sterile medications.

The device is provided sterile and is intended for single-use.

The KIRO Set is not intended to be used for direct patient contact.

V. INDICATIONS FOR USE

The KIRO Set is a sterile, single-use disposable ancillary device used with the peristaltic pumps in the KIRO Oncology pharmacy compounding device for the transfer of fluids into sterile powder drug vials for reconstitution of intravenous drugs or into sterile medication containers for intravenous drug administration.

The device is for prescription use only.

The KIRO Set and its predicate device are intended to be used with their respective pharmacy compounding devices by trained health-care personnel in the hospital pharmacy environment for the transfer of solutions for pharmaceutical preparations. Both devices are not intended to be connected directly to patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the KIRO Set and the predicate device are tubing sets with similar inlets and outlets for connection to source containers and vials or final medication containers. Both the subject and predicate devices are based upon the same technological elements:

- Tubing Set – Both are based upon medical grade tubing



- Source Connections – Both have filtered vented bag spike connected by luer lock to the tubing
- Final Connections – Both have male luer lock connections available at the outlet end allowing for connection to dosing spikes for vials and to reservoirs such as infusion bags, cassettes and elastomeric pumps
- Both are closed systems not having any contact of the fluid pathway with any reusable part of the pharmacy compounding device

The following technological differences exist between the KIRO Set and predicate devices:

- Use in a peristaltic pump for fluid transfer for the KIRO Set as compared to an integrated syringe for the predicate
- KIRO Set uses silicone tubing as compared to PVC tubing in the predicate
- The KIRO Set uses the external waste container of the KIRO Oncology device to contain the priming waste as compared to the integrated waste container for the predicate device.

Substantial Equivalence Comparison Table – KIRO Set, Predicate Device Sets Gri-Fill 3.0 and Reference Device

Characteristics	KIRO Set	Sets Gri-Fill 3.0 (K050339) Predicate Device	Baxa Tubing Sets (for Pharmacy Pump) (K872743) Reference Device
Indications for Use	<p>The KIRO Set is a sterile, single-use disposable ancillary device used with the peristaltic pump in the KIRO Oncology pharmacy compounding device for the transfer of fluids into sterile powder drug vials or into sterile medication containers for intravenous drug administration.</p> <p>The device is for prescription use only.</p>	<p>SETS GRI-FILL 3.0 1 WAY and 2 WAY fluid transfer sets are ancillary devices used in conjunction with the GRI-FILL 3.0 pharmacy compounder in the hospital pharmacy to provide a fluid pathway through which one or two substances are delivered into a final IV container or syringe.</p> <p>SETS GRI-FILL 3.0 MULTIPLE fluid transfer sets are ancillary devices used as fluid pathways in conjunction with the GRI-FILL 3.0 pharmacy compounder and associated 1 WAY or 2 WAY transfer sets through which the same substance from up to 6 source containers may be delivered into a final</p>	<p>The Repeater Pump tube set is part of the Repeater Pump device. This device provides peristaltic pump driven fluid transfer that facilitates repeatable drug dosage distribution and reconstitution in hospital pharmacies. The Repeater Pump tube set provides the fluid pathway and pumping mechanism for the pump system. The device is for use with IV bags, syringes, elastomeric infusers, and other drug administration containers. Some sets are sold sterile and others are not based on the end use of the set.</p>

		IV container. The device should not be used with lipids. The device is intended to be used by trained health-care personnel. It is restricted to sale by or on the order of a physician.	
Intended Use	This product would be used for fluid transfer in the preparation final medication containers and the reconstitution of drug vials in hospital pharmacies when used with the KIRO Oncology pharmacy compounding device.	This product would be used for fluid transfer in the preparation of final medication containers or syringes, and the reconstitution of drug vials in hospital pharmacies when used with the GRI-FILL 3.0 pharmacy compounding device.	This product would be used for fluid transfer in hospital pharmacies when used with the Repeater Pump for the filling of oral dispensers, luer syringes, vials, elastomeric infusers, minibags, cassettes and the reconstitution of drug vials.
Product Code	LHI	LHI	FMF
Regulation No.	21 CFR 880.5440	21 CFR 880.5440	21 CFR 880.5860
Classification	Class II	Class II	Class II
SUBSTANTIAL EQUIVALENCE BASED UPON INTENDED USE			
Use	Single Use	Single Use	Single Use
Prescription / OTC use	Prescription Use	Prescription Use	Prescription Use
Pharmacy Compounding Device Specified	KIRO Oncology	GRI-FILL 3.0	Repeater Pump (The Repeater Pump is a classified as a Piston Syringe (880.5860) and not a pharmacy compounding device
Intended for Direct Connection to Patient	NO	NO	NO
Use environment	Hospital pharmacy inside the KIRO Oncology PCD ISO 5 environment.	Hospital pharmacy both outside and inside of flow hoods	Hospital pharmacy both outside and inside of flow hoods.
Target users	Trained health-care personnel	Trained health-care personnel	Trained health-care personnel
Sterility	Sterile; Non-pyrogenic fluid pathway	Sterile; Non-pyrogenic fluid pathway	Sterile
Sterilization	Gamma Radiation	Ethylene Oxide	Ethylene Oxide
Biocompatibility	Per ISO 10993-1:2010 for prolonged duration, indirect blood path	Not known	Not known

	contacting device		
Acceptable Fluids	Saline (0.9% sodium chloride), 5% glucose, WFI or any aqueous diluent which is adequate for the dilution of drugs into the right concentration for intravenous administration	Not to be used with lipids	No limitations provided for acceptable fluids
SUBSTANTIAL EQUIVALENCE BASED UPON TECHNOLOGICAL CHARACTERISTICS			
Biocompatibility	Per ISO 10993-1:2010 for prolonged duration, indirect blood path contacting device	Not known	Not known
Acceptable Fluids	Saline (0.9% sodium chloride), 5% glucose, WFI or any aqueous diluent which is adequate for the dilution of drugs into the right concentration for intravenous administration	Not to be used with lipids	No limitations provided for acceptable fluids
Primary Fluid Contact Material - Tubing	Medical Grade Silicone	PVC with DEHP	Medical Grade PVC Resin with Medical Grade Silicone section in contact with peristaltic pump
Fluid Transfer Mechanism	External Peristaltic Pump – Double Channel	Integrated Syringe – Single Channel	External Peristaltic Pump – Single Channel
Closed system (fluid not in contact with any reusable part of the compounding device)	YES	YES	YES
Dose Range	0.5 ml to 200 ml	2.0 ml to 3000 ml	Minimum dispensing volume of 0.2 ml
Accuracy	Doses into vials: 5.0 ml to 100 ml: $\pm 5\%$ 1.0 ml to 4.99 ml: $\pm 10\%$ 0.5 ml to 0.99 ml: ± 0.1 ml Doses into reservoirs: 50 ml to 200 ml: $\pm 10\%$ 10 ml to 49.99 ml: ± 2 ml	Doses from 2.0 ml to 25.0 ml: $< \pm 0.5$ ml Doses from 25.0 ml to 3000 ml: $< \pm 2\%$	Volume accuracy: $\pm 10\%$ @ 0.2 ml $\pm 5\%$ @ 0.4 ml $\pm 2\%$ @ 1.0 ml
Number of diluent/source	One	One container with 1	One



containers		WAY set Two containers with 2 WAY set Up to 6 containers with MULTIPLE set	
Integrated Waste Container	NO	YES	NO
Connections to Source Containers	Vented bag spike or male luer	Vented bag spike or male luer	Vented bag spike
Connections to Final Containers	Male Luer Connector	Male Luer Connector Also supplied with female to female luer to allow for female to male luer connection	Male Luer Connector
Final Containers	Vials, Infusion Bags, Cassettes, Elastomeric pumps	Vials, Syringes, Elastomeric pumps, Gri-bag, Gri-flex	Oral dispensers, Syringes, Vials, Elastomeric pumps, minibags, cassettes

VII. PERFORMANCE DATA

Performance testing was conducted in accordance with FDA Guidance for Industry and FDA Staff – “Intravascular Administration Sets Premarket Notification Submissions [510(k)],” July 11, 2008 and to address any technological differences with the predicate device.

Biocompatibility Testing

The biocompatibility evaluation for the KIRO Set device 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,” as recognized by FDA; and FDA Guidance for Industry and FDA Staff – “Intravascular Administration Sets Premarket Notification Submissions [510(k)],” July 11, 2008. Biocompatibility testing as required for External Communicating Devices, Blood Path, Indirect Contact, Prolonged Duration was conducted in accordance with cited guidances and standards.

The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Acute systemic toxicity
- Material-mediated pyrogenicity
- Hemocompatibility – Hemolysis Indirect and Hemolysis Direct
- Pyrogen testing

Media Fill Testing

A media fill study was conducted to demonstrate that the KIRO Set does not allow for microbial ingress into the internal fluid pathway during its use under worst-case use conditions in the KIRO Oncology pharmacy compounding device (PCD). The study design considered the test method described in ISO 13408-1:2008, Aseptic processing of health care products – Part 1: General requirements and Chapter 71 of the USP for Sterility Testing of Compounded Sterile Preparations (CSPs).

Media fill cycles of drug vials and reservoirs filled using the KIRO Set in the KIRO Oncology PCD reconstitution station using soybean casein digest broth (TSB) as the source diluent were designed to represent the worst-case use conditions which have the maximal potential for allowing microbial contamination of the KIRO Set internal fluid pathway. These simulations included conditions for the maximum number of connections to be expected in an 8-hour use session with simulated interruptions due to user errors.

The TSB filled vials and reservoirs and corresponding negative and positive controls were placed in incubation at the end of each working session for 7 days at 22°C with an additional 7 days at 35°C. The samples were visually inspected for turbidity indicating growth of microorganisms in the TSB culture medium for up to 14 days after incubation. Positive controls were found to be turbid after a minimum of 3 days of incubation at 22°C.

None of the media fill simulation vials or reservoirs filled using the KIRO Set showed any turbidity, thereby indicating that no growth of microorganisms occurred. The media fill study conducted demonstrates that the use of the KIRO Set does not present a risk for microbial ingress into the internal fluid path.

Performance Testing

- Physical and Chemical Testing per ISO 8536-4 including Leakage/Tensile Strength Testing
- Physical Testing of Luer Locks per ISO 594-2
- Accuracy of Delivered Doses
- Stability of the KIRO Set in the KIRO Oncology Peristaltic Pump
- Distribution Testing

VIII. CONCLUSIONS

The performance testing conducted demonstrates that the KIRO Set performs substantially equivalent to the predicate device. Both the KIRO Set and the predicate device have the same intended use. The KIRO Set performance testing supports that any technological differences with the predicate device do not raise any different questions of performance for the device when compared to the predicate device.