June 1, 2018

Colonic Plus
Rosa Alvarez
Owner
73-925 Hwy. 111, Ste. L
Palm Desert, CA 92260

Re: K180800
Trade/Device Name: Colonic Plus Regular, Small, and Straight Shape Hydrokits
Regulation Number: 21 CFR§ 876.5220
Regulation Name: Colonic Irrigation System
Regulatory Class: II
Product Code: KPL
Dated: March 30, 2018
Received: April 4, 2018

Dear Rosa Alvarez:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K180800

Device Name
Colonic Plus Regular, Small, and Straight Shape Hydrokits

Indications for Use *(Describe)*
The use of this device is restricted to colon cleansing when medically indicated, such as before radiological or endoscopic examination.

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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Colonic Plus	Technical Evaluation Documentation	**# Document** **Colonic Plus Hydrokits**
Section 05: **Traditional 510(k) Summary**		

DATE OF SUBMISSION: **03/20/2018**

SUBMITTER NAME: Colonic Plus

SUBMITTER ADDRESS: 73-925 HWY 111, STE L
Palm Desert, CA 92260
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DEVICE TRADE NAME: Colonic Plus Regular, Small and Straight Shape Hydrokits
COMMON NAME: COLONIC IRRIGATION SYSTEM
CLASSIFICATION NAME: COLONIC IRRIGATION SYSTEM (21 CFR 876.5220)
Procode: KPL
Regulatory Class: II

PREDICATE DEVICE: **Transcendencias Comerciales, S.L. K131852- Hydrokit**
Trade Name: Transcom Colon Hydrotherapy Models HC-1 and HC-1 Classic And Hydrokit

Device Description: Colonic Plus Hydrokits

The Colonic Plus Regular, Small and Straight shape Hydrokits is a plastic, non-sterile, single use product colonic irrigation system that is used as an accessory with lower bowel Colonic irrigation systems intended to instill water into the colon through a nozzle inserted 2"-3" into the rectum to evacuate the contents of the lower colon.

Technical Characteristics Compared to the Predicate Device:

The proposed Colonic Plus Regular, Small and Straight shape Hydrokits (See Figues 3A-3C) are substantially equivalent in intended use, indications for use, design and material used in the Transcoms Hydrokit manufactured by Transcendenicas Comerciales, S.L(K131852) (See figure 3D). The only differences between the new device and the predicate device is that the ring on the obturator is crescent and on the predicate device is round and that the tip of the obturator is slightly wider on the new device. Lastly on the Colonic Plus Straight shape speculum, it has no curve and is slightly thinner than the predicate device.

- See diagrams below

Proposed Devices:

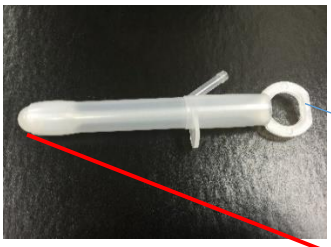

Figure 3A: Colonic Plus Regular Hydrokit

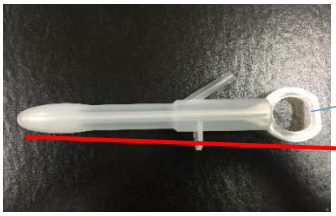

Figure 3B: Colonic Plus Small Hydrokit

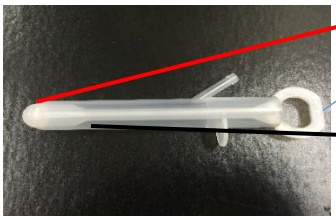

Figure 3C: Colonic Plus Straight Shape Hydrokit

Crescent Ring

Slightly wider insertion tip

No bulb/curve, ultimately slightly thinner

Predicate Devices:

Figure 3D: Transcom Hydrokit (K131852)

Round ring

Proposed Kit Components

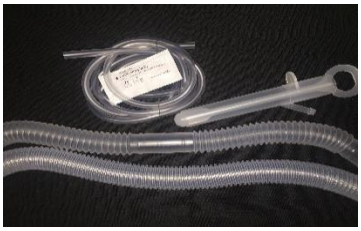

Figure 4A: Colonic Plus Hydrokit (K163040)

Predicate device Kit Components

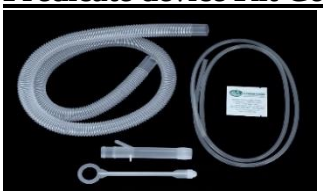

Figure 4B: Transcom (K131852)

Kit Components packaged with the proposed disposable Colonic Plus Regular, Small and straight shape Hydrokit (plastic water line, EVA corrugated and segmented waste hose, & surgical lubricant) are substantially equivalent to those included with the Transcom Hydrokit manufactured by Transcendencias Comerciales, S.L. (K131852) (See figure 4A above)
Surgical Lubricant: Dynarex Sterile Lubricating Jelly
K092488

INTENDED USE COMPARED TO THE PREDICATES DEVICE:
The device is intended for use to cleanse the colon when medically indicated, such as before radiological or endoscopic examination. It has the same intended use as predicate devices Transcom Hydrokit Manufactured by Trascendencias Comerciales, S.L. (K131852).

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

The Colonic Plus Regular, Small, and Straight Shape Hydrokits are substantially equivalent in indications for use, intended use, design and material as that of the Transcoms Hydrokit (K131852). The water pressure leakage test and the Tensile & Compression tests performed on the finalized Colonic Plus Hydrokits were passed according to our acceptance criteria and were substantial equivalent to the predicate device. We also submitted our finalized Colonic Plus hydrokits (Speculum, Obturator, and PVC water line) to American Preclinical Services for Biocompatability Testing on Cytotoxicity, Irritation and Sensitization which have all passed.

SUMMARY DISCUSSION OF CLINICAL DATA:
No clinical studies are submitted to support this premarket notification.

CONCLUSION:
We believe the intended use, the indications for use, the design, materials used, the functionality and the operation of the speculum kit is essentially the same as the predicate devices: Transcoms Hydrokit (K131852). Hence, substantial equivalence of the The Colonic Plus Regular, Small and Straight shape Hydrokits with the legally marketed device may be established.