March 2, 2022

Gnali Bocia S.R.L.
Katy Gnali
External Consultant
Via Brescia, 41/M-N
Lumezzane, 25065
ITALY

Re: K201861
Trade/Device Name: Bio Fluff System
Regulation Number: 21 CFR 876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: Class II
Product Code: KPL
Dated: February 23, 2022
Received: February 28, 2022

Dear Katy Gnali:

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/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 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 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,

Je Hi An, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K201861

Device Name
Bio Fluff System, models HT and HTP

Indications for Use *(Describe)*
The Bio Fluff System is intended for colon cleansing to remove fecal residues 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.**

# 510(k) Summary - K201861

**Applicant:**


| | |
|---|---|
| Company Name: | Gnali Bocia S.R.L. |
| Company Address: | Via Brescia, 41/M-N<br>25065 Lumezzane (BS)<br>ITALY |
| Company Phone: | +39 030-871498 |
| Official Contact for Correspondence: | Katy Gnali |
| Phone: | +39 030-871498 |
| E-mail: | regulatorybiofluff@gnalibocia.it |


**Date Summary Prepared:** October 11, 2021

**DEVICE IDENTIFICATION**

| | |
|---|---|
| Device name: | Bio Fluff System, models HT and HTP |
| Generic/ Common Name: | Colonic Irrigation System |
| Classification number: | 21 CFR§ 876.5220, Class II |
| Classification name: | Colonic Irrigation System |
| Product Code: | KPL |
| Product Code Name | Colonic Irrigation System |
| Regulatory Class | Class II |
| Device Panel: | Gastroenterology/Urology |

**PREDICATE DEVICE:**

Aqua Cleanse, Quality Medical Supply, K150381

**DEVICE DESCRIPTION**

The Bio Fluff System is intended to instill water through a disposable speculum into the colon.
Intestinal Cleansing is carried out by inserting water in the patient's rectum at controlled temperature and pressure through the disposable specula. This action allows the cleaning of the lower tract of the colon.
The Bio Fluff System comprises:
- different models of the Bio Fluff device:
  - HT model, for professional use,
  - HTP model, portable version of HT model,
- associated components:
- disposable HT specula for both Bio Fluff model HT and Bio Fluff model HTP.

**INDICATIONS FOR USE**

The Bio Fluff System is intended for colon cleansing to remove fecal residues when medically indicated, such as before radiological or endoscopic examination.

**DISCUSSION OF NON-CLINICAL TESTS**

Non-clinical tests were conducted to demonstrate substantial equivalence to the predicate device. The test results demonstrated that the proposed device complies with the applicable sections of the standards listed below:

Biocompatibility

Biocompatibility testing was performed on both models (HT and HTP) of the final finished device. The biocompatibility studies were conducted by third party laboratory on all components that contact patients directly or indirectly. The following tests were performed:

a. Cytotoxicity: ISO 10993-5: 2009
b. Sensitization: ISO 10993-10: 2010
c. Irritation: ISO 10993-10: 2010

The devices do not arise any issues of biocompatibility for their intended use.

Bench tests

Functional testing showed correct operation of the Bio Fluff System as per its intended use, specifically including:

- Pressure Safety
- Flow Control
- Temperature Safety
- Leak Resistance.

**SUBSTANTIAL EQUIVALENCE**

The Bio Fluff System is substantially equivalent in indications for use, intended use, design and material as those of the predicate Aqua Cleanse (K150381).

Both the subject and the predicate device are intended to introduce warm filtered water into the colon through a speculum inserted into the rectum to assist with the evacuation of the contents of the lower colon, they fill and empty water into and out of the colon thus cleansing it of its contents.

In further support of a substantial equivalence determination, hereunder is a comparison chart with the submitted device and the predicate device.

| **SPECIFICATIONS** | **Subject device:**<br>**Bio Fluff System** | **Predicate device:**<br>**Aqua Cleanse K150381** | **CONCLUSION** |
|---|---|---|---|
| Manufacturer | Gnali Bocia S.r.l. | Quality Medical Supply | |
| Common name | colonic irrigation system | colonic irrigation system | |
| Indications For Use | The Bio Fluff System is intended for colon cleansing to remove fecal residues when medically indicated, such as before radiological or endoscopic examination. | This device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examination. | substantially equivalent: colon cleansing implies removal of fecal residues. |
| Classification | 21 CFR§ 876.5220 | 21 CFR§ 876.5220 | same |
| Product code | KPL | KPL | same |
| Intended User | Bio Fluff models HT and HTP are for professional use in medical environments, trained healthcare practitioner | Aqua Cleanse is for professional use only | Same |
| Insertion point | Anus | Anus | same |
| Antibacterial Filters | yes | yes | substantially equivalent |
| Flow regulator | yes | yes | same |
| Temperature gauge | yes | yes | same |
| Temperature safety | Thermostatic valve enacts when water temperature reaches 38 °C<br>Thermostatic mixer for the regulation of water temperature | Mixing valve to maintain water temperature | substantially equivalent |
| Flow control | Flowmeter<br>excess flow valve | flow control valve | substantially equivalent |
| Pressure Gauge | yes | yes | same |
| Pressure control | Safety valve opens at 200 mbar (2.90 pounds per sq. inch (psi) | Safety valve<br>allow 3.00 pounds per sq. inch | substantially equivalent |
| Timer | Yes | yes | substantially equivalent |
| Outgoing waste material observation | little window for inspection | glass observation tube | substantially equivalent |
| Circuit cleaning system | yes<br>can be activated when the device is not being used for treatment | yes<br>can be activated when the device is not being used for treatment | substantially equivalent |

| | | | |
|---|---|---|---|
| Electrical components | no | yes | this difference does not affect the safety or effectiveness of the subject device; the performances of the two devices are substantially equivalent |
| Biocompatibility | ISO 10993-1 compliance | ISO 10993-1 compliance | substantially equivalent |
| Performance test | • Pressure Safety<br>• Temperature Safety<br>• Leak Resistance<br>• Flow control | • Pressure Safety<br>• Temperature Safety<br>• Electrical Safety<br>• Leak Resistant | substantially equivalent<br>There are no electronic components in the subject device, thus electrical safety is not to be tested |

**SUBSTANTIAL EQUIVALENCE DISCUSSION:**

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

The subject and predicate devices have similar design and same intended use

The subject and predicate devices are based on the same or similar technological elements and are made with the materials largely used for the same type of medical devices already on the market.

The minor differences in the technological characteristics of the devices do not impact the safety and effectiveness of the subject device. The performance data demonstrate that the subject device is as safe and effective as the cited predicate.

**CONCLUSION:**

Based on the available information, the Bio Fluff System is substantially equivalent to the existing legally marketed predicate device under Federal Food, Drug and Cosmetic Act.