K072831
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(h) 510 (k) Summary

Submitter's name: Karla N Coombs
21 Union Turnpike
Branchville, NJ 07826
973-948-3796

DEC 12 2008

Contact person: Karla N Coombs

Date prepared: October 2, 2007

Name of device: Dosage vessel to be used with a indwelling feeding tube.

Trade name: FROG = Fluids- Rx( medications)- On the- Go
See Logo on label information

Equivalence data: The FROG is functionally similar to the syringe used for delivery of "bolus feedings and medications through a naso-gastric feeding tube or a "Peg" feeding tube. By adapting the tip of the syringe barrel to accommodate the secondary medication tubing, adding a cap and hanger and enlarging the barrel of the syringe to accommodate the 240cc capacity, the FROG is capable of delivering a can (240cc) of feeding or medications, hands free and accurately without spillage or waste.
The FROG is made of polypropolene, latex free and dishwasher safe for home use.
The drip chamber on the delivery tubing allows for back priming in the event crushed medication particles clump and cause a blockage in the flow.
The syringe currently used to give medications

(h) 510 k Summary continued

does not accommodate any alternative in this area and the caregiver has no choice but to disconnect the syringe from the patient's feeding tube and risk loss of medication or feeding in the process.

In a single clinical test, the 60cc syringe tip was shortened and a secondary medication tubing was inserted into the tip to provide a more controllable (using the roller clamp) flow rate for a client who was capable of giving self feedings and medications. The reflux continued to be a problem, with no untoward effects physically on the client and in subsequent non-clinical testing, the airway on the tubing, the cap and hanger have proven to resolve these issues as well. The plunger was not used, as bolus feedings and medication are to be given by gravity. *

A clinical test of the "FROG" with cap and hanger was performed via the "BUTTON" access, popular for use in children. The ease and accuracy of use was reported and the level of anxiety related to fear of inaccurate dosing was relieved.

*Perry & Potter-Clinical Nursing Skills & Techniques-5 the Edition.

(h) 510 k Summary continued

In conclusion, the FROG, will prove to be a welcomed relief to those already burdened with the inability to eat and swallow as they have done under normal circumstances in the past. This device will allow them and their caregivers more freedom to go about their activities of daily living with less disruption in their routine and ease in their ability to be medicated, hydrated and nourished.

Respectively submitted,

Karla N Coombs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2008

Karla N. Coombs, R.N.
Owner
Newby-Coombs, L.L.C.
21 Union Turnpike
P.O. Box 20
BRANCHVILLE NJ 07826

Re: K072831
Trade/Device Name: The FROG Device
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FPD
Dated: November 25, 2008
Received: December 2, 2008

Dear Ms. Coombs:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K072831

Device Name: The FROG Device

Indications for Use:

A non-sterile gravity medicine delivery device for use with a nasogastric or percutaneous endoscopic gastrostomy ( PEG) tube to administer crushed and diluted medications and liquids.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072831