



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Mr. Lev Melinyshyn  
President  
Uresil, LLC  
5418 W. Touhy Avenue  
SKOKIE IL 60077

FEB 23 2010

Re: K093653

Trade/Device Name: Uresil Gastrostomy Catheter Kit  
Regulation Number: 21 CFR §876.5980  
Regulation Name: Gastrointestinal tube and accessories  
Regulatory Class: II  
Product Code: KNT  
Dated: November 19, 2009  
Received: November 25, 2009

Dear Mr. Melinyshyn:

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 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). 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

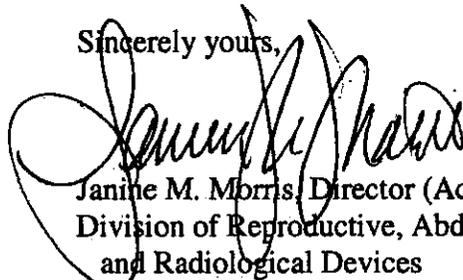
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Janine M. Morris, Director (Acting)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

K093653  
191

#### 4. Indications for Use

510(k) Number (if known): K093653

Device Name: **Uresil Gastrostomy Catheter Kit**

Indications for Use:

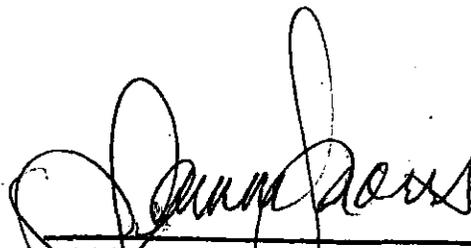
The Uresil Gastrostomy Catheter Kit is indicated for gastroenteric feeding or drainage.

Prescription Use   x   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (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 K093653

Page 1 of 1