DEC 1 4 2012

Pre-market Notification for OXTI Inflation Devices

510(k) Summary of Safety and Effectiveness

1. Submitter

OXTI Corporation.

8th Floor, Unit 146, Jian 1st Road, Jhonghe District

New Taipei City, TAIWAN 23585

Contact:

Mr. John Sung

Phone: +886 2 2225 4998 Ext. 20

2. Name and Classification of Device

Trade Name:	OXTI Inflation Device
Common/Usual Name:	Balloon inflation syringe
Classification Name:	Angiographic injector and syringe
Regulation Medical Specialty:	Cardiovascular
Review Panel:	Cardiovascular
Classification Number:	21CFR 870.1650
Product Code:	MAV

3. Predicate Device

Trade Name	510(k) Number	Decision Date
Dolphin Inflation Device	K042449	5/20/2005
Indeflator Plus 30 Priority Pack	K962495	9/12/1996

4. Device Description

The device consists of three major components; a) 30ml barrel, b) inflation mechanism and c) 6% standard conical fitting and stopcocks system for connecting to the PTCA catheter. The barrel has graduation markings at 0.5ml interval to the full 30ml capacity A dual scale pressure gauge mounted at distal end of the barrel is capable of indicating pressure up to 30atm at 1atm or 10psi intervals. Reinforced polyurethane tubing extending from the syringe exit port connects to a 6% male/female conical fitting for attaching to the 3-way stopcock and to the angiographic catheter.

5. Indications for Use

The OXTI Inflation Device is indicated for use during cardiovascular procedures to create, maintain, and monitor pressure in a balloon dilation catheter.

6. Technological Characteristics

The 30 ml barrel is made of polycarbonate for clarity and added strength against high system pressure. The pressurization system and the plunger are made of high impact resistant polypropylene. Controlled inflation and deflation is achieved by manually pushing or pulling the plunger. A unique locking latch secures the plunger in place to maintain a constant pressure even if the user lets go of the device. High-pressure polyurethane tubing provides links from the inflation barrel to the angioplastic catheter using a 6% conical locking connector.

7. Performance Summary

- The whole device has been tested for material biocompatibility as listed below:
  - Cytotoxicity;
  - Sensitization;
  - Intracutaneous reactivity;
  - Acute systematic toxicity; and
  - Hemocompatibility.
- Functional aspects and performance characteristics of the inflation device are verified through a series of bench tests which include:
  - 6% conical fitting efficacy, per ISO 594.1 & 2;
  - Whole device resistance to water leakage;
  - Tubing joints resistance to tensile pull;
  - Barrel and plunger resistance to water leakage; and
  - Forces to initiate and continue pushing of plunger;
- Pressure gauge accuracy was tested against a standard, calibrated gauge at 2atm pressure intervals for up to 30atms.

Results of various tests support the claim that the OXTI Inflation Device meets requirements specified by various international voluntary standards and is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Oxti Corporation
c/o Joseph Chang
Consultant
7128 Staffordshire Street
Houston, Texas 77030

DEC 1 4 2012

Re: K122152
Trade/Device Name: OXTI Inflation Device
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: Class II
Product Code: MAV
Dated: October 31, 2012
Received: November 5, 2012

Dear Mr. Chang:

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 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,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K122152

Device Name:
OXTI Inflation Device

Indications for Use:
The OXTI Inflation Device is indicated for use during cardiovascular procedures to create, maintain, and monitor pressure in the balloon dilation catheter.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122152