Pre-market Notification for YOMURA Safety I.V. Catheters

Date: August 27, 2011

FEB - 8 2012

**510(k) Summary of Safety and Effectiveness**

**1. Submitter**

YOMURA Technologies Inc.
No. 2-3, Kung 8th Road, Second Industrial Park
Linkou District, Taipei 244
TAIWAN

Contact:
Ms. Sherry Lin
Phone: +886 2 8601 3839 Ext. 253

**2. Name and Classification of Device**

| | |
|---|---|
| Trade Name: | YOMURA Safety I.V. Catheters |
| Common/Usual Name: | IV Catheter |
| Classification Name: | Catheter, intravascular, therapeutic, short term, less than 30 days |
| Regulation Medical Specialty: | General Hospital |
| Review Panel: | General Hospital |
| Classification Number: | 21CFR 880.5200 |
| Product Code: | FOZ |

**3. Predicate Device**

| Trade Name | 510(k) Number | Decision Date |
|---|---|---|
| PROTECTIV 2000 I.V. Catheter Safety System | K962226 | 12/23/1996 |
| Insyte Autoguard Catheter | K000235 | 4/5/2000 |

**4. Device Description**

The Yomura Safety I.V. Catheter consists of a catheter connected to a standard conical fitting, and a safety mechanism. Upon activation of the safety mechanism the needle

guard covers the entire length of the needle. Therefore, the risks of needle stick injuries can be reduced.

**5. Indications for Use**

The YOMURA Safety I.V. Catheter is to be inserted into patient's vascular system for short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously.

**6. Technological Characteristics**

The YOMURA Safety I.V. Catheter consists of an over needle peripheral catheter made of polyurethane material with radiopaque stripes. The stainless steel needle is placed in the catheter to maintain rigidity and to facilitate venipuncture. A safety mechanism constitutes a needle guard is built inside the device. Upon insertion and threading of the catheter, the needle guard extends to full length and locks into place to encapsulate the entire length of the needle. Thus adds in the prevention of accidental needle stick injuries.

**7. Performance Summary**

Various bench tests were performed to ensure that the Yomura Safety I.V. Catheter meets all functional and performance requirements for its intended use. Material biocompatibility is verified by performing all required tests specified by ISO 10993 for "external communicating, circulating blood, prolonged exposure" devices. Functional and performance tests were also carried out according to ISO 10555.1 and 10555.5. Safety feature was tested according to requirements provided by a guidance document issued by US FDA "Medical devices with sharps injury prevention features" issued on August 9, 2005.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Yomura Technologies Incorporated
C/O Ms. Sherry Lin
No. 2-3, Kung 8th Road, Second Industrial Park
Linkou District, New Taipei City 244
Taiwan

FEB - 8 2012

Re: K112542
Trade/Device Name: YOMURA Safety I.V. Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Catheter, Intravascular, therapeutic, short term, less than 30 days
Regulatory Class: Class II
Product Code: FOZ
Dated: January 30, 2012
Received: February 1, 2012

Dear Ms. Lin:

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,

for Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

## Indication for Use

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

**Device Name:**
YOMURA Safety I.V. Catheter

**Indications for Use:**
The YOMURA Safety I.V. Catheter is to be inserted into patient's vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids intravenously.

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

for REC Feb 9, 2012

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



510(k) Number: K112542