K032141

JAN 2 8 2004

II. 510(K) Summary of Safety and Effectiveness (Per 21 CFR 807.92)

1. General Information

Establishment

■ Manufacturer:	Tiger Meditech Incorporated
■ Address:	12F, No. 130, Chung-Hsiao E. Rd. Sec. 2 Taipei 100 Taiwan
■ Registration Number:	3004022299
■ Contact Person:	Dr. Ke-Min Jen Official Correspondent 886-3-5208829 (Tel) 886-3-5209783 (Fax)
● Date Prepared:	October 19, 2003

Device

● **Proprietary Name:**	Tiger Meditech SecuMax™ Blood Collection System
● **Common Name:**	Vacutainer System
● **Classification Name:**	Tubes, Vials, Systems, Serum Separators, Blood Collection, Class II, JKA

2. Safety and Effectiveness Information

- **Predicate Device:**

  Claim of Substantial Equivalence (SE) is made to Becton Dickinson Vacutainer Systems (K980098)

- **Device Description:**

The SecuMax ^{TM} Blood Collection System is a single-use sterile blood collection system. There are three main components in the package, i.e., sterile hypodermic needle, sterile Luer adapter, and sterile Luer type holder. Special N-typed ergonomic luer adapter can eliminate the collection angle by placing the needle nearly parallel with the arm. The special design luer adapter can be used with any size of hypodermic needle. Push-off Luer holder is designed to fit N-typed luer adapter. The hypodermic needle used is Exel International disposable hypodermic needles with 510K # **861153**.

- **Intended Use:**

The SecuMax^{TM} Blood Collection System is a sterile and single-use package consisting of a sterile Luer holder with a sterile Luer adapter to hold Exel hypodermic needles during venipuncture.

- **Synopsis of Test Methods and Results**

Bench, pyrogen test, sterility, substantial equivalence, and simulated clinical testing are employed upon submission of this 510(K) premarket notification according to the General Guidance document provided by CDRH/ FDA.

- **Substantial Equivalence (SE)**

A claim of substantial equivalence is made to Becton Dickinson Vacutainer Systems (**K980098**). The Tiger Meditech SecuMax^{TM} Blood Collection System and the Becton Dickinson Vacutainer Systems both offer a simple and effective way to collect blood. The Tiger Meditech SecuMax^{TM} Blood Collection System utilizes multi-sample Luer adapter with sterile Luer holder and hypodermic needle. The

Becton Dickinson Vacutainer Systems utilizes conventional straight holder and hypodermic needle. The intended purposes of both Tiger Meditech SecuMax™ Blood Collection System and the Becton Dickinson Vacutainer Systems are to collect blood while dispose the entire device as a unit in a sharps container.

Ke-Min Jen, Dr.

Official Correspondent for

Tiger Meditech Incorporated

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2004

Tiger Meditech Incorporated
C/O Dr. Shu-Chen Cheng
ROC Chinese-European Industrial Research Society
2064 Tamarin Drive
Columbus, Ohio 43235

Re: K032141
Trade/Device Name: Tiger Meditech™ SecuMax Blood Collection System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle-Accessory
Regulatory Class: II
Product Code: FMI
Dated: October 29, 2003
Received: November 3, 2003

Dear Dr. Cheng:

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.

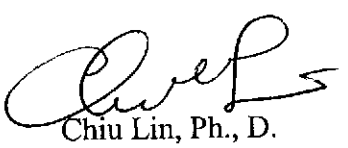
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032141

IV. Indications for Use Statement

Applicant: Tiger Meditech Incorporated.

510(k) Number: **K032141**

Device Name: Tiger Meditech SecuMax™ Blood Collection System

Indications for Use:

The SecuMax™ Blood Collection System is a sterile and single-use package consisting of a Luer sterile holder with a Luer adapter to hold Exel hypodermic needles during venipuncture. The entire device will be disposed as a unit in a sharps container.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _

Per 21 CFR 801.109 (Optional Format 1-2-96)

Vicki Hubbard Interim Branch Chief

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

510(k) Number: K032141