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11.0-510 (k) Summary

Summary of Safety and Effectiveness for Tuta's Blood/Solution Administration Set

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Assigned 510(k) number K023039

1. **Manufacturer's Name:** **Tuta Healthcare Pty. Limited**

   Manufacturer's Address: 318-332 Burnsbay Road
   Lane Cove , Sydney NSW 2066
   Australia

   Contact Person: Omid Souresrafil PhD

   Telephone Number: + 61 2 94270300 (Switchboard)
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   Date: 10/09/02

2. **Device Name:**
   Trade Name: Blood/Solution Administration Set
   Proprietary Name: Tuta Healthcare Blood/Solution Administration Set
   Classification Name: Administration Set, Intravascular as Per CFR 21 880.5440

3. **Legally Marketed Equivalent Device**

   The, **Blood/Solution Administration Set** in the submission is substantially equivalent to **Baxter Healthcare's Solution Administration Set (K924721).**

The Tuta Healthcare Pty. Limited Blood Administration Set is a device used to administer fluids, blood and blood products from a container to a patient's vascular system Through a catheter or venous access system inserted into a vein.
Use of Needle-Free Access site may aide in the prevention of needlestick injury.

Description of the intended use of the Device

The Tuta Healthcare Blood/Solution Administration Set is designed administer fluids from a container to a patient's vascular system through a needle catheter inserted into a vein. The pump helps to control the rate of flow of fluids from the container to the patient.

4. Summary of Similarities and Differences in Technological Characteristics, Performance and intended use

The 510(k) "Substantial Equivalence Decision Making Process (Detailed)" decision tree was utilized to make a determination of the substantial equivalence.

1. Does the new device have the same indication statement?

Yes. The Blood/Solution Administration Set and Baxter Healthcare's Solution Administration Set have the same indications for use being "administration of fluids from a container to a patient's vascular system through a needle catheter inserted into a vein.

2. Does the new device have the same technological characteristics, e.g. Design Materials.

Yes. The design of the Blood/Solution Administration Set and Baxter Healthcare's Solution Administration Set are similar in terms of components of , PVC tubing, roller regulators and perforators.
There are no differences in the principle of operation of the Blood/Solution Administration Set and Baxter Healthcare's Solution Administration Set.

3. Could the new characteristics Affect Safety or effectiveness?

No new characteristics.

4. Are the descriptive characteristics precise enough to Ensure equivalence?

Yes. The descriptive characteristics of the Tuta Healthcare Blood/Solution Administration Set and Baxter Healthcare's Solution Administration Set are enough to ensure equivalence.

5. Are performance data available to Assess Equivalence?
Yes. Laboratory bench testing has been performed to assess the new device as compared to the devices proposed to be substantially equivalent.
The testing included the following:

- Flow rate testing of the Blood/Solution Administration Set as compared to Baxter Healthcare's Solution Administration Set.

Additionally, biocompatibility testing, performed in accordance with the General Program Memorandum #G95 , has been conducted on all materials of the Blood/Solution Administration Set which are utilized in the fluid path.

6. Does the Performance data demonstrate equivalence?

Yes. Based upon the results of the laboratory testing, the performance of the Blood/Solution Administration Set compares favourably to that of the current marketed Baxter Healthcare's Solution Administration Set.

Results from the biocompatibility testing have shown the materials of the Blood/Solution Administration Set are suitable for limited contact.

CONCLUSION:

Based upon the above information, the Blood/Solution Administration Set are substantially equivalent to Baxter Healthcare's Solution Administration Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

Dr. Omid Souresrafil
Tuta Healthcare Pty. Limited
318-332 Burns bay Road
Lane Cove, Sydney NSW 2066
AUSTRALIA

Re: K023039
Trade/Device Name: Blood/Solution Administration Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: BRZ
Dated: September 10, 2002
Received: September 12, 2002

Dear Dr. Souresrafil:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. STATEMENT OF INDICTIONS FOR USE

510(k) Number (if known): K023039

Device Name: Blood/Solution Administration Set

Indications For Use: Administration of Intravenous fluids and drugs.

The Tuta Healthcare Pty. Limited Blood Administration Set is a device used to administer fluids, blood and blood products from a container to a patient's vascular system Through a catheter or venous access system inserted into a vein.
Use of Needle-Free Access site may aide in the prevention of needlestick injury.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ()
(Per 21 CFR 801.109)

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

510(k) Number: K023039