Section 5 510(K) Summary

K073444

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

510(k) number: K043235

AUG 18 2008

Submitter's Identification:	Triton Medical, LLC
Submitter Address:	9810 South Dorchester Avenue Chicago, IL 60628
Submitter Phone:	646.723.6907
Submitter Fax:	212.697.0806
Submitter Contact:	Ross Kurz Vice-President rkurz@tritonmed.com (email)

2. Name of the Device:
Triton Medical TMed IV-Set

3. Predicate Device Information:
Dragon Heart Intravascular Administration Set
510(k) Number: K043235
Dragon Heart Medical Devices Co., Ltd.
Kaiping, Guangdong, 529375
Peoples Republic of China

4. Intended Use:
The Triton Medical TMed IV-Set is used to administer fluids from a container to a patient through a needle or catheter inserted into a vein.

5. Device Description:
Depending on configuration, the device may include the following; protective cap(s), drip chamber, tubing, back check valve(s), anti-siphon valve, needle free Y-site, roller clamp, 0.22 micron filter or 1.2 micron filter, male Luer lock, spike, and medi-hook.

Schematics representations of the various configurations of the Triton Medical TMed IV-Set are exhibited in Appendix 3 – Device Drawings and Configurations.

The Triton Medical TMed IV-Set is supplied sterile.

6. Comparison to Predicate Devices:

Technical characteristics of the device compared to the predicate device:

	Triton Medical TMed IV-Set	Dragon Heart Intravascular Administration Set K043235
Manufactured By	Dragon Heart Medical Device Co., Ltd	Dragon Heart Medical Device Co., Ltd
Intended Use	Administer fluids from a container to a patient through a needle or catheter inserted into a vein	Administer fluids from a container to a patient through a needle or catheter inserted into a vein
Device Class	II	II
Product Code	FPA	FPA
Components	Tubing, a flow regulator, drip chamber, backflow valve, anti-siphon valve, male Luer lock, 0.22 micron filter or 1.2 micron filter, connectors between parts of the set, needle free Y-site, spike, and medi-hook.	Tubing, a flow regulator, drip chamber, backflow valve, anti-siphon valve, male Luer lock, 0.22 micron filter or 1.2 micron filter, connectors between parts of the set. needle free Y-site, spike, and medi-hook
Sterilization	Ethylene Oxide according to standard; ISO 11135, Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization, 1994.	Ethylene Oxide according to standard; ISO 11135, Medical Devices- Validation and Routine Control of Ethylene Oxide Sterilization, 1994.
Packaging	According to Standard: ISO 11607, Packaging for Terminally Sterilized Medical Devices, 2000.	According to Standard: ISO 11607, Packaging for Terminally Sterilized Medical Devices, 2000.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

The device is the same device as the predicate. It is manufactured by the same manufacturer, from the same materials, and to the same specifications as the predicate. Any testing is identical.

8. Discussion of Clinical Tests Performed:

Not applicable

9. Conclusions:

The subject device has the same intended use, manufacturer, and technical characteristics as the predicate device. Similarly, there are no differences in materials used to fabricate the subject device and the predicate device. Therefore no new questions of safety or effectiveness are raised by this submission. Thus, the Triton Medical TMed IV-Set is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Triton Medical LLC
C/O Mr. Ian P. Gordon
Senior Vice President
Emergo Group
1705 South Capitol of Texas Highway, Suite 500
Austin, Texas 78746

AUG 1 8 2008

Re: K073444
Trade/Device Name: Triton Medical TMed IV-Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: August 7, 2008
Received: August 11, 2008

Dear Mr. Gordon:

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.

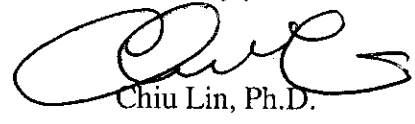
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Section 4 Indications for Use

Indications for Use

510(k) Number: K073444

Device Name: Triton Medical TMed IV-Set

Indications for Use:

The Triton Medical TMed IV-Set is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

The device is for prescription use only.

Prescription Use √ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (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
Office of Device Evaluation and Safety

510(k) Number: K073444