K123551

MAY 1 4 2013

5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the iTClamp™ device is provided below.

Device Common Name:	Vascular Clamp
Device Proprietary Name:	iTClamp™
Submitter:	Innovative Trauma Care, Inc. 3463 Magic Dr., Suite 120 San Antonio, Texas 78229
Contact:	Richard Waite Sr. Director of Quality Assurance/ Regulatory Affairs, 3463 Magic Dr., Suite 120 San Antonio, TX 78229 Office: 210-582-5850 ext. 1932 FAX: 210-582-5851 Cell: 214-662-9277 rwaite@innovativetraumacare.com
Date Prepared:	November 16, 2012
Classification Regulation:	870.4450
Panel:	Cardiovascular
Product Code:	DXC
Predicate Device	K102025 – Combat Ready Clamp Combat Medical Systems LLC

Indication for Use

The iTClamp™ is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla and inguinal areas.

Device Description

The ITClamp™ is a clamp device that quickly controls critical bleeding by closing the skin to create a temporary, contained hematoma until surgical repair. The ITClamp is a self-locking surgical clamp with suture needles that penetrate the skin to evert the skin edges between pressure bars of the device and anchor it to the skin to reduce slippage and leakage. Pressure is evenly distributed across the bars, which seal the skin over a wound. An adjustable locking mechanism increases or decreases pressure across the wound to achieve a fluid tight seal.

The ITClamp™ controls bleeding by sealing the skin closed to apply direct pressure and create a temporary pool of blood (hematoma) under pressure. This permits formation of a stable clot until the patient can receive medical care and/or surgical repair.

The device is provided sterile and is for single use.

The ITClamp™ consists of the following components:

1) Suture needles
2) Plastic Shell
3) Locking mechanism
4) Lock release mechanism

Biocompatibility Testing
Biocompatibility testing was performed according to ISO 10993 including, cytotoxicity, acute system toxicity, muscle implantation and pyrogenicity. Results confirmed that the materials used in the ITClamp™ are safe for its intended use.

Performance Testing - Bench
Results from the performance testing were provided. The laboratory performance testing was conducted to verify suitability of the design characteristics of the device. The testing consisted of the following: Extreme Temperature Evaluation, Tensile and Compression Test, Torque, and Needle (Bend and Pull). Results of the testing confirmed the ITClamp™ met design requirements.

Performance Testing - Animal
Animal testing was performed in a porcine model to assess ITClamp™ performance in a lethal junctional bleed model. The ITClamp™ resulted in statistically significant improvements in survival, survival time, and blood loss when compared with controls or packing with standard gauze. Tissue damage was not observed by histological examination after 3 hours of application.

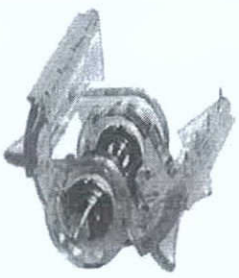
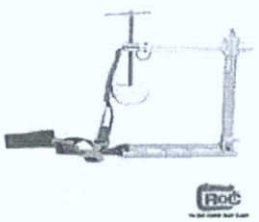
Performance Testing- Distribution/Aging/Packaging Integrity

Distribution Challenge Testing and Accelerated Aging Studies were completed to ensure that product integrity is maintained for the intended use. Due to the complexity and non-standard packaging system, microbial aerosol testing was performed to prove the structural integrity of the packaging unit. All testing preformed resulted in no nonconformance(s).

Substantial Equivalence

A comparison of the ITClamp to the predicate devices is provided below. Like the predicate devices, the ITClamp is intended to control bleeding through the application of direct pressure. Also like the predicate Combat Ready Clamp, the ITClamp is intended to provide emergency control of severely bleeding vascular wounds until medical and/or surgical repair can be obtained. The ITClamp has different technology than the predicate device. The ITClamp applies pressure to the severely bleeding wound by sealing off the skin surrounding the wound, which leads to blood pooling under pressure and eventual clotting. The predicate device, the Combat Ready Clamp, also applies direct pressure but this is achieved by a applying an external mechanical clamp above the inguinal area to stop blood flow into the area. Although the technology of the proposed device differs from the predicate, it does not raise any new or different types of safety or effectiveness questions.

The available performance data demonstrate that the ITClamp is safe and performs effectively in achieving hemostasis for severely bleeding wounds. The ITClamp, therefore, is substantially equivalent to other devices regulated under 21 CFR 870.4450.

	New Device	Predicate Device
510(k) Number	K123551	K102025
Classification / Procode	870.4450 / DXC	870.4450 / DXC
Device Name	ITClamp™	Combat Ready Clamp
Manufacturer	Innovative Trauma Care, Inc.	Combat Medical Systems
Indication for Use	The ITClamp™ is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla and inguinal areas.	The Combat Ready Clamp is indicated for use in the battlefield to control difficult bleeds in the inguinal area.
Device Design	ITClamp is a self-locking surgical clamp with suture needles that penetrate the skin to evert the skin edges between pressure bars of the device and anchor it to the skin to reduce slippage and leakage. Pressure is evenly distributed across the bars, which seal the skin over a wound. An adjustable locking mechanism increases or decreases pressure across the wound to achieve a fluid tight seal or wound closure as desired.	The CRoC (Combat Ready Clamp) is designed to control difficult bleeds in the inguinal region. The CRoC can be used in a tactical environment where traditional methods of hemorrhage control are not possible and standard tourniquets cannot be applied. It provides compression to large vessels and direct pressure to difficult wounds thus controlling hemorrhage and eliminating the need for manual pressure. It is an expandable aluminum clamp that is durable, collapsible, light weight, and easily removed.
Device Operation	Application of pressure by applying clamp to temporarily seal wound site	Application of pressure by applying mechanical clamp
Picture		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 14, 2013

Innovative Trauma Care, Inc.
C/O Richard Waite
3463 Magic Dr., Suite 120
San Antonio, Texas 78229

Re: K123551
Trade/Device Name: iTClamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: April 5, 2013
Received: April 9, 2013

Dear Mr. Waite:

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,

Bram D. Zuckerman -S

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

4.0 Indications for Use Statement

510(k) Number (if known): K123551

Device Name: ITClamp™

Indications For Use:

The ITClamp™ is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla and inguinal areas.

Prescription Use _X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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