



Food and Drug Administration
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April 30, 2015

Innovative Trauma Care, Inc.
Ian Atkinson
Chief Technology Officer
3463 Magic Dr., Suite 120
San Antonio, TX 78229

Re: K150813
Trade/Device Name: iTClamp50
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: March 25, 2015
Received: March 31, 2015

Dear Ian Atkinson:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,


Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150813

Device Name

iTClamp®50

Indications for Use (Describe)

The iTClamp®50 is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla, inguinal areas, scalp, and neck.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Special 510(k): Device Modification
Innovative Trauma Care, Inc.
iTClamp[®]50

6.0 510(k) Summary

In accordance with 21 CFR 807.92 the 510(k) Summary for the iTClamp50 is provided below.

Device Common Name: Vascular Clamp

Device Proprietary Name: iTClamp50

Submitter: Innovative Trauma Care, Inc.
3463 Magic Dr., Suite 120
San Antonio, TX 78229

Contact: Ian Atkinson, Chief Technology Officer

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Date Prepared: March 25, 2015

Classification Regulation: 870.4450

Panel: Cardiovascular

Product Code: DXC

Predicate Device K140805 – iTClamp50, 510(k) Clearance October 9, 2014

Indication for Use

The iTClamp50 is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla, inguinal areas, scalp and neck.

Device Description

The iTClamp50 is a clamp device that quickly controls critical bleeding by closing the skin to create a temporary, contained hematoma until surgical repair. The iTClamp50 is a self-locking surgical clamp with suture needles that penetrate the skin to evert the skin edges (similar to sutures or staples) 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.

Special 510(k): Device Modification
Innovative Trauma Care, Inc.
iTClamp[®]50

The iTClamp50 controls bleeding by sealing the skin closed to apply direct pressure to the cut edges of the skin 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 iTClamp50 consists of the following components:

- 1) Suture needles
- 2) Tray w/Tyvek lid
- 3) Locking mechanism
- 4) Lock release mechanism

Substantial Equivalence

The modified iTClamp50 has the following similarities to the previous version of the iTClamp (predicate), which have previously received 510(k) concurrence (K140805):

- Have the same indicated use
- Have the identical shelf life of 4 years
- Use the same operating principle and fundamental scientific technology
- Incorporate the same basic design
- Have the same materials making point of contact with user and patient

Like the predicate device, the iTClamp50 is intended to control bleeding through the application of pressure to compressible areas (where application of direct pressure will control bleeding) in the scalp, extremities, and all junctional areas (inguinal areas, axilla and neck). It is not intended for internal bleeding into the chest or abdomen. The updated iTClamp50 is the same device that was previously cleared in K140805 in that it provides temporary bleeding control to wounds in the scalp, extremities, and all junctional areas (inguinal areas, axilla and neck) until medical and/or surgical repair can be obtained. The iTClamp50 (also the predicate) applies pressure to the severely bleeding wound by sealing off the everted skin surrounding the wound by direct external contact with the plastic pressure bar, which leads to pressure on the cut edges of the skin, allowing blood to pool under pressure and eventually resulting in clot formation.

The modified iTClamp50 has the following technological modifications compared to the predicate:

- 1) Mechanical change to the one-way locking mechanism
- 2) Material change to the one-way locking mechanism (non-patient contacting)
- 3) Mechanical change to the lock release mechanism

Special 510(k): Device Modification
 Innovative Trauma Care, Inc.
 iTClamp[®]50

- 4) Modifications to the opposing arms for improved grip
- 5) Updated packaging from a polypropylene calm shell to a polypropylene tray with a tyvek lid.

The modified iTClamp raises no new or different types of effectiveness or safety questions. There is no change to the fundamental scientific principles of the technology. Design verification and validation testing has demonstrated that the device meets predefined acceptance criteria and is substantially equivalent to the previously cleared device. This testing was conducted to verify suitability of the design characteristics of the device and provide evidence that the final design of the product meets previously established and cleared finished product specifications. The design verification and validation activities consisted of the following:

1. Leakage Test- to verify that the device can create a liquid tight seal.
2. Minimum Holding Torque - to verify that the force applied to the device during function does not deform the needles or damage the pressure bars.
3. Needle Pullout Force Test – to verify that the needle pullout force of the device is within specification
4. Maximum Arming Force Test – to verify that the force required to arm the device is within specification
5. Maximum Closing Force Test – to verify that the force required to close the device is within specification
6. Button Disengaging Force Test – to verify that the force required to release the device is within specification
7. Operational Environmental Tests – to verify the function of the device within specified environments.
8. Usability Tests – to verify the technological modifications did not affect end-user usability of the device.
9. Package Testing – to verify that the updated packaging met specifications for sterility.

Based on the design verification and validation test results, the iTClamp50, is substantially equivalent to the iTClamp50 classified under 870.4450.

A comparison of the new technologically modified iTClamp50 to the previous version of the iTClamp (predicate) is provided below.

	Subject Device	Predicate Device
510(k) Number	TBD	K140805
Classification / Procode	870.4450 / DXC	870.4450 / DXC

Special 510(k): Device Modification
 Innovative Trauma Care, Inc.
 iTClamp[®]50

	Subject Device	Predicate Device
Device Name	iTClamp50	iTClamp50
Manufacturer	Innovative Trauma Care, Inc.	Innovative Trauma Care, Inc.
Indication for Use	same	The iTClamp50 is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla, inguinal areas scalp and neck.
Device Design	same	iTClamp50 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.
Device Operation/ Fundamental Scientific Principle	same	Application of pressure by applying clamp to temporarily seal wound site
One-way locking mechanism	One-way double-row ratchet	One-way clutch
Packaging	Polypropylene tray with Tyvek lid	Polypropylene clam shell
Arm	Inner and outer arm are textured, introduction of thumbhole, increased surface area to improve grip	Arm contains texturized gripping bar

Special 510(k): Device Modification
Innovative Trauma Care, Inc.
iTClamp[®]50

	Subject Device	Predicate Device
Picture	 A clear plastic medical device with a prominent red circular component in the center. It has a complex, multi-lobed shape with several protrusions and recesses.	 A clear plastic medical device, similar in design to the subject device but without the red component. It features a similar multi-lobed structure with a central opening.