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™50 indication for use is provided below.

Device Common Name:	Vascular Clamp
Device Proprietary Name:	iTClamp™50
Submitter:	Innovative Trauma Care, Inc. 3463 Magic Dr., Suite 120 San Antonio, TX 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:	July 31, 2013
Classification Regulation:	870.4450
Panel:	Cardiovascular
Product Code:	DXC
Predicate Device	K123551 – iTClamp™ K012219 – ScalpFix Clip System

OCT 2 8 2013

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

The purpose of this 510(k) is to modify the already cleared indication for use to include use of the device on the scalp.

Device Description
The iTClamp™50 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/scalp 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.

The iTClamp controls bleeding by sealing the skin/scalp closed to apply direct pressure to the cut edges of the skin/scalp 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

Additional Biocompatibility Testing is not necessary to support the modified indication for use. Physical composition of the product and packaging has not changed in anyway; therefore biocompatibility testing is not necessary to support this 510(k).

Performance Testing - Bench

Additional bench performance testing is not necessary. The physical composition of the product, packaging and sterilization has not changed in any way. Therefore, the bench testing provided in the previous 510(k) (K123551) is applicable and no additional bench testing is necessary.

However, Innovative Trauma Care has performed cadaver testing to demonstrate substantial equivalence of the iTClamp50 for the new proposed indication for use. The protocol and results for the cadaver study are provided in Appendix C. Cadaver models were tested to ensure the safety and effectiveness of the iTClamp50 device. Predicate testing was also performed to ensure that the device performed as intended. Both the testing of the comparison between the predicate device and the iTClamp™ and the safety and efficacy of the iTClamp™ on the scalp identified no additional risks. The results of the Cadaver Study identifies that the device is suitable for use on the scalp

Performance Testing – Animal

Animal Performance Testing is not necessary to demonstrate substantial equivalence of this device for the new indication for use. An animal study of scalp bleeding is ineffective in that animal scalp bleeds do not hemorrhage at a comparable rate of human scalp hemorrhaging and therefore are ineffective models. In place of animal testing, Innovative Trauma Care, Inc. used a cadaver study to show the effectiveness and safety of the device on the scalp as

well as compared the device to the predicate, ScalpFix Clip System. Please see Appendix C for the Cadaver Study.

Performance Testing – Clinical Study

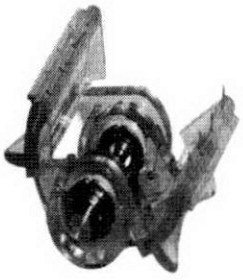
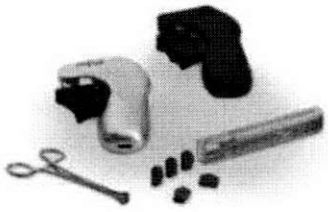
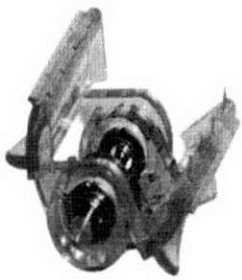
Not applicable. Clinical data is not necessary to establish the substantial equivalence of the device.

Substantial Equivalence

A comparison of the iTClamp50 to the predicate devices is provided below. Like the predicate devices, the iTClamp50 is intended to control bleeding through the application of pressure. Also like the predicate ScalpFix Clip System, the iTClamp50 is intended to provide temporary control of severely bleeding scalp wounds until medical and/or surgical repair can be obtained. The iTClamp50 has similar technology to the predicate device. The iTClamp50 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, blood pooling under pressure and eventual clotting. The predicate device, the ScalpFix Clip System, also applies temporary pressure to the wound edge(s) by use of a handheld mechanical applicator to affix the ScalpFix Clip. The iTClamp is applied by using the clinician's hand to actuate the device in order to stop blood flow at the scalp wound. Although the predicate technology utilizes an applicator there are no significant differences in technology in that pressure is utilized to stop blood flow at the point of injury (scalp) in both products. Neither the predicate nor the iTClamp™ raise any new or different types of safety or effectiveness questions.

The available performance data demonstrate that the iTClamp50 is safe and performs effectively in achieving hemostasis for bleeding scalp wounds. The iTClamp50, therefore, is substantially equivalent to the iTClamp50 classified under 870.4450 (procode DXC) as well as the ScalpFix Clip System classified under 21 CFR 882.4150.

	Subject Device	**Predicate Device**	**Predicate Device**
510(k) Number	TBD	K012219	K123551
Classification / Procode	870.4450 / DXC	882.4150 / HBO	870.4450 / DXC
Device Name	iTClamp™50	ScalpFix Clip System	iTClamp™50
Manufacturer	Innovative Trauma Care, Inc.	Aesculap, Inc.	Innovative Trauma Care, Inc.
Indication for Use	The iTClamp50 is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla, inguinal areas and scalp.	Aesculap's ScalpFix Clip System is indicated for use in temporary hemostasis of the scalp edge.	The iTClamp50 is a trauma clamp device for the temporary control of severe bleeding in the extremities, axilla and inguinal areas.

	Subject Device	Predicate Device	Predicate Device
Device Design	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.	The scalp clips are used for temporary hemostasis of the open scalp. It has proven useful to use plastic clips to ligate the scalp during trepanation or large exposures of relatively long durations, thereby avoiding bleeding at the wound margin. Aesculap Scalp Clips are intended for single use only. They may not be re-sterilized. The scalp clips are packaged as 10 scalp clips per magazine in the box of 20 magazines.	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	Application of pressure by applying clamp to temporarily seal wound site	Application of pressure by applying scalp clamp to wound edge	Application of pressure by applying clamp to temporarily seal wound site
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

October 28, 2013

Innovative Trauma Care Inc.
Richard Waite
3463 Magic Dr.
Suite 120
San Antonio, TX 78229 US

Re: K132651
Trade/Device Name: iTClamp 50
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: October 3, 2013
Received: October 16, 2013

Dear Richard 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 contact 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. 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 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

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K132651

Device Name: iTClamp™

Indications For Use:

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

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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