

**510(k) Summary
SAM Medical Products, Inc.
SAM® Junctional Tourniquet**

JUL 24 2013

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the SAM® Junctional Tourniquet (SJT) device is provided below.

The assigned 510(k) number is: K131561

Contact Details

Applicant Name: SAM Medical Products, Inc

SAM Medical Products, Inc
27350 SW 95th Avenue, Suite 3038
Wilsonville, OR 97070

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Contact: Jack N. McCutcheon
QARA Manager

Email: jack.mccutcheon@sammedical.com

Date Prepared: May 10, 2013

Device Name

Trade Name: SAM® Junctional Tourniquet

Common Name: Vascular Clamp

Classification Name: Clamp Vascular

Predicate Device: K123694, SAM® Junctional Tourniquet

Device Description

The SAM Junctional Tourniquet addresses the issue of non-tourniquetable inguinal hemorrhage and axilla hemorrhage. The device is designed to control bleeding in the inguinal area or axilla area where standard tourniquets cannot be used. The SAM Junctional Tourniquet is used to control bleeding for up to 4 hours.

A key feature of the device is a belt/buckle system which provides feedback to the user after a minimum circumferential force around the patient is obtained, after which an inflatable Target Compression Device (TCD) is manually activated to occlude an artery or to provide compressive force over a Hemostatic agent.

The SAM Junctional Tourniquet can also be used as a Circumferential Pelvic belt for pelvic fracture immobilization.

Intended Use/Indications for use

The SAM Junctional Tourniquet is indicated for battlefield and trauma situations:

- To control difficult bleeds in the inguinal area.
- To control difficult bleeds in the axilla area.
- To immobilize a pelvic fracture.

Substantial Equivalence Comparison

The SAM Junctional Tourniquet (SJT) is similar in design and intended use to the marketed product manufactured by:

SAM Junctional Tourniquet (SJT), SAM Medical Products

	<u>SJT Attribute:</u>	<u>New Submission:</u>	<u>Cleared (K123694)</u>
1	Target Population: Trauma Patients	Yes	Yes
2	Indicated for use to control difficult bleeds in the inguinal area	Yes	Yes
3	Indicated for use to control difficult bleeds in the axilla area	Yes	No
4	Indicated for immobilization of pelvic fractures	Yes	Yes
5	Product code	DXC	DXC
6	Circumferential belt	Yes	Yes
7	Point pressure	Yes	Yes
8	Point pressure mechanism	Manual, Pneumatic	Manual, Pneumatic
9	Force control mechanism	Identical, Spring Controlled Buckle	Spring Controlled Buckle

	<u>SJT Attribute:</u>	<u>New Submission:</u>	<u>Cleared (K123694)</u>
10	Materials	Identical, Metal, Injection Molded Plastic, Textile	Metal, Injection Molded Plastic, Textile
11	Biocompatibility	Yes, per ISO 10993-1 requirements	Yes, per ISO 10993-1 requirements
12	Shelf Life	N/A	N/A
13	Sterile Product	No	No
14	Performance Testing	Cadaver, Bench	Cadaver, Bench

Non-clinical Testing

Bench Testing:

- Cadaver
- TCD Four Hour Stability Test

Clinical Testing

No clinical testing was performed.

Conclusion

The SAM Junctional Tourniquet with the additional indication for use (to control difficult bleeds in the axilla area) is substantially equivalent to the SAM Junctional Tourniquet cleared under 510(k) K123694. It is of equivalent design and materials, it addresses the same patient population, it has the same mechanism of action and it uses no new technology. The new indication for use does not introduce new safety or performance concerns.



July 24, 2013

SAM Medical Products, Inc.
C/O Jack N. McCutcheon
Quality Assurance and Regulatory Affairs Manager
27350 SW 95th Avenue, Suite 3038
Wilsonville, OR 97070

Re: K131561

Trade/Device Name: SAM[®] Junctional Tourniquet
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: May 28, 2013
Received: May 30, 2013

Dear Mr. McCutcheon:

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" (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,



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: K131561

Device Name: SAM® Junctional Tourniquet

Indications for Use:

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- To control difficult bleeds in the inguinal area.
- To control difficult bleeds in the axilla area.
- To immobilize a pelvic fracture.

Prescription Use X
(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 IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. G. Hillbremer