K112874 OCT 17 2011
1 of 2

SECTION 5
510(K) SUMMARY

Submitted on behalf of:

Company Name: **Dominion Medical Devices, LLC**
Address: **818 N. Oak**
Guthrie, OK 73044

Telephone: 405-755-5308
Fax: 405-232-9659

by: **Elaine Duncan, M.S.M.E., RAC**
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082

Telephone: 715-549-6035
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CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: **October 12, 2011**
TRADE NAME: **EZ Vein inflatable tourniquet**
COMMON NAME: **inflatable tourniquet**
CLASSIFICATION NAME: **pneumatic tourniquet**
PRO CODE: **KCY**

SUBSTANTIALLY EQUIVALENT TO: The EZ Vein™ inflatable tourniquet is substantially equivalent to both the non-pneumatic tourniquet such as the Degania Silicone Tourniquet (K875092) and a pneumatic accessory device, like the DeRoyal's Pneumatic Tourniquet Cuff (K953953). The similarities are the inflatable cuff technology.

DESCRIPTION of the DEVICE: The EZ Vein inflatable secondary tourniquet is made with soft fabric and flexible plastic to form an inflatable bladder. The integral Velcro attachment strips secure the EZVein around an appendage in the same way as would a blood pressure cuff. Dimensions have been chosen to wrap around most anyone's arm, but an extension is included to allow the EZVein to work on lower limbs or with large arms. The Vein Access Window allows the health care professional to position the EZVein over the target vein for access for IV drip, blood draw or injection. The EZVein cuff is applied after the initial conventional non-inflatable tourniquet (such as latex tubing) is applied. The initial tourniquet, as is conventional, blocks the return of venous blood through the major veins to the heart, but the application of the EZVein inflatable cuff helps move the blood in deep tissues into the veins to help them to distend for easier visualization and access. This may aid the medic desiring venous access to more accurately and rapidly achieve the desired aim.

K112874
2 of 2

510(k) Summary-Continued

INDICATIONS FOR USE: The EZvein™ inflatable secondary tourniquet is used in conjunction with a non-pneumatic tourniquet, to enhance the presentation of veins for access (blood draw or IV administration.)

SUMMARY of PERFORMANCE TESTING: Conventional pneumatic tourniquets are more typically used in surgery to reduce bleeding and higher compression pressures may be required. In contrast, the EZVein™ cuff is not intended to be used without a primary non-pneumatic tourniquet, and has been tested to demonstrate that the Velcro™ strip self-releases between 195 mmHg and 220 mmHg, in order to ensure that the EZVein™ cannot be over-inflated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 17 2011

Dominion Medical Devices, LLC
% Paladin Medical, Inc.
Elaine Duncan, M.S.M.E., RAC
P.O. Box 560
Stillwater, Minnesota 55082

Re: K112874
Trade/Device Name: EZ Vein Inflatable Tourniquet
Regulation Number: 21 CFR 878.5910
Regulation Name: Pneumatic tourniquet
Regulatory Class: Class I
Product Code: KCY
Dated: September 29, 2011
Received: September 30, 2011

Dear Ms. Duncan:

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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

Indications for Use:

The EZvein™ inflatable secondary tourniquet is used in conjunction with a non-pneumatic tourniquet, to enhance the presentation of veins for access (blood draw or IV administration.)

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)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112874