值得信赖的精准
创新的历史

Valleylab™ FT10 能量平台
产品信息套件

Medtronic
Further, Together

A HERITAGE
YOU CAN TRUST

The Valleylab™ 能量平台

您可以对近50年来优质的能量产品和手术领域的创新充满信心。 日复一日，在全球各地的外科手术场上提供信心。对我们坚定不移地致力于积极的患者结果的信心。

Valleylab™ 能量产品组合提供业内基于能量的外科手持设备套件1 - 从一系列值得信赖的电外科工具到采用LigaSure™技术的先进血管闭合仪器和为其提供动力的发生器设备。

现在，我们很高兴能够提供基于能量的手术设备的新的：Valleylab™FT10能量平台。

VALLEYLAB™ FT10能量平台
性能与精密

Valleylab™ FT10 能量平台不仅推动了我们全系列的基于能源的设备，而且使它们比以往更好。[2,3]

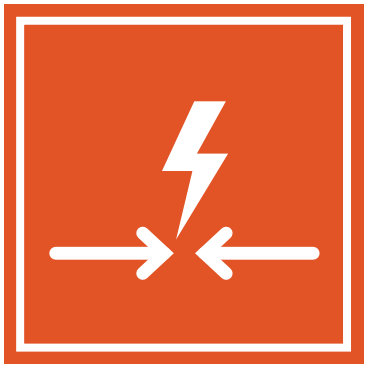
通过更快的闭合和切割时间提高我们所有设备的性能 - 例如，LigaSure™血管闭合速度提高50%[4] — the Valleylab™ FT10能量平台提供精确的能量[3]

高级创造力

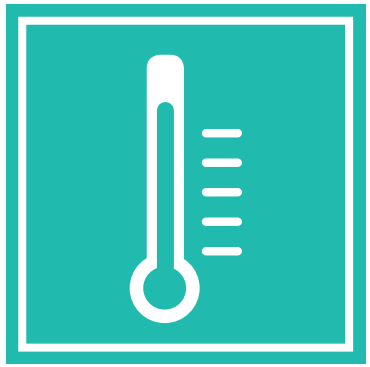
Valleylab™能源产品组合中同类先进能量和电外科设备均由智能发生器提供动力，可通过精确算法管理能量输送。Valleylab™FT10能量平台的技术进步改善了整个产品组合的所有外科应用。[2,3]

新一代的变化

LigaSure™ 技术通过以下方式得到改进：



闭合时间快达50%[4]



下颌口温度[5]

电外科表现更精确[3]：

自动双极具有更快的激活时间[6]

单极性能得到改善[3]

更智能

Valleylab™FT10能量平台内置的智能TissueFect™组织传感技术通过实时读取组织成分，提高了手持设备的速度和一致性[7]

TissueFect™技术每秒检测设备性能434,000次，监测组织阻抗并实现有效和高效的能量输送.[7] 该技术仅适用于Valleylab™发生器，可驱动所有电外科和先进的双极功能。

特征	Valleylab™ FT10 能量平台	ForceTriad™ 能量平台
TissueFect™ 组织传感技术	读取组织：每秒434,000次	读取组织：每秒3,333次
软件升级	以太网连接（具有尚未启用的WiFi功能）	串行端口连接
双极电缆补偿	读取电缆长度和宽度，以获得一致的ES输出	不可用
触摸屏	单一，简化的触摸屏[9]	每种模式有三个触摸屏
新的ES设置	软凝	现有的ES设置
性能	▪ 降低钳口温度[5] ▪ 更快的闭合时间（3-6秒,ForceTriad™能量平台时为1-4秒）[10] ▪ 自动功率设置需要少的设置并小化手术期间进一步处理的需要[9] ▪ 简单，直观的控制和信息显示[9]	▪ 为竞争设备设定标准的性能

外形尺寸

重量(kg)	10.1	13.6
宽 (cm)	35.8	45.8
高 (cm)	17	25.25
深 (cm)	46.25	50.8

510(K) CLEARANCE

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

September 10, 2015

Covidien
Ms. Sharon McDermott
Senior Regulatory Affairs Product Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K151649
Trade/Device Name: Valleylab™ FT10 Electrosurgical Platform
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 17, 2015
Received: June 18, 2015

Dear Ms. McDermott:

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" (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 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

外科手术申请表

Valleylab™能源产品组合提供业内大的基于能量的外科手持设备套件 - 从一系列值得信赖的电外科工具到采用LigaSure™技术的先进血管闭合设备和为其提供动力的发电设备。[1]

与**ForceTriad™**能量平台相比，新的**Valleylab™FT10**能量平台为我的程序提供了更高的速度和一致性：

- 更快的LigaSure™血管闭合性能[4]
- 更精确的电外科能量输送[3]

它还提供了一个简化的平台：

- 单个触摸屏[9]
- 占地面积小[9]
- 易于培训的功能[11]

我有信心使用一种技术平台，该平台为全球数百万程序中使用的设备组合提供动力。 感谢您查看此信息。 如果您有任何疑问，请随时与我联系。

此致，

订购信息

VLFT10GEN	**Valleylab™ FT10 能量平台**
VLFTCRT	**Valleylab™ FT10 台车**

1. 基于ES和Advanced能源产品目录，与Ethicon的当前目录相比较。
2. 与ForceTriad™能量平台相比。 基于Valleylab™FT10服务手册：部件号PT00016329，REV 2015年1月。.
3. 用于评估单极性能的离体测试模型。 基于Covidien离体单极报告："验证 - 报告 - Valleylab™FT10猎户座的离体单极程序流量评估。"2014年11月; R0064443 Rev A..
4. 用于评估闭合时间的台架测试模型。 基于Covidien备忘录："用于VLFT10白皮书的LigaSure数据源。"2015年9月; RE00025819 Rev A.
5. 用于评估装置温度的离体猪台架测试模型。 基于Covidien验证报告："LigaSure Thermal Profile Valleylab FT10"。
6. 基于Covidien产品验证报告："Autobipolar Evaluation - Valleylab™FT10"; 2015年2月;RE0064455。
7. 基于Valleylab™FT10服务手册：部件号1079477，REV 2015年1月。
8. 用于评估闭合时间的台架测试模型。 基于Covidien备忘录："用于VLFT10白皮书的LigaSure数据源。"2015年9月; RE00025819 Rev A.
9. Valleylab™ FT10 能量平台用户指南，2014年; 部件号PT00016328。
10. 基于Covidien验证报告："LigaSure Thermal Profile Valleylab FT10"R0064462 Rev B.
11. 基于Covidien产品验证报告："模拟使用中Valleylab™FT10外科医生和护士评估的产品验证"2015年1月至2月;RE00005401。

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