How to Process Power Supplies when Applying for China FDA Approval

医疗设备申请 CFDA，电源如何处理

As an important part of medical equipment, the power supply plays an important role in the user's medical equipment. Similarly, when the medical equipment is submitted for safety agency certification, the power supply must also be tested or reviewed.

电源作为医用设备的重要部件，在用户的医用设备整机中有重要的作用，同样，在医用设备整机申请安规时，电源也是必须要进行测试或者审查的部件。

In the America or Europe, the safety test report or certificate of the medical power supply can be obtained separately, so that the certification body can adopt and approve the certificate of the power supply when the user equipment is tested, which can save time and cost.

在美洲或者欧洲，电源时可以单独取得医用标准的测试报告或者证书，这样在用户整机设备进行医疗标准的测试时，认证机构可以采用和认可该电源的证书，这样可以节约时间和费用。

China, Japan, South Korea, Australia, and New Zealand have no specific medical standard or test method for medical components such as power supplies. In these countries, power supplies or accessories cannot be used as a complete medical device or accessory to obtain the medical safety certificate of that country. Currently the common practice is that the power supply manufacturer will obtain the CB report relating to the medical standard, and then cooperate with the medical device manufacturer of the end use equipment to apply for the medical standard of the complete medical device in the corresponding country.

但在一些国家，如中国，日本，韩国，澳洲，新西兰，没有像美国UL，欧洲TUV那样对电源等医用配件有一个专门的医疗标准的测试方法。也就是说，在这些国家，电源类配件是无法作为一个整机或者配件来拿到相应国家的医疗标准证书的。目前通用的做法是电源会拿到医疗标准的CB，然后配合客户的整机设备去相应国家作整机的医用标准的申请。

The following describes how the power supply, as a component, safety approval can be obtained in China with the medical device manufacturers complete system or equipment.

下面介绍下电源如何在中国配合整机设备拿到医用证书。

In China, the certification authority for medical equipment is the China Food and Drug Administration (CFDA). In March 2018, considering the particularity of drug regulation, the state has separately established the State Drug Administration. The English name is officially identified as NMPA, or National Medical Products Administration.

To learn more about NMPA, please visit the website: http://www.nmpa.gov.cn.

You can also refer to the following URL to learn about the CFDA:

https://www.emergobyul.com/resources/videos-china-market-overview

在中国，医用设备的证书发放机构为国家食品药品监督管理总局(China Food and Drug Administration)，简称CFDA，2018年3月，考虑到药品监管的特殊性，国家单独组建了国家药品监督管理局，其的英文名称正式确定为NMPA。NMPA的全称为国家药品监督管理局(National Medical Products Administration)。

要了解更多关于NMPA信息，请查询网站：http://www.nmpa.gov.cn

也可以参考如下的网址去快速了解CFDA的一些信息：https://www.emergobyul.com/resources/videos-china-market-overview

In the following article, for the convenience of the reader, we still use the acronym CFDA .

在下面的文章中，为了阅读方便，在下面的介绍中我们仍然使用CFDA的名称。

CLASSIFICATION OF MEDICAL EQUIPMENT

Medical device grade requirements can be divided into three categories.

The first category refers to medical devices that are sufficiently managed to ensure their safety and effectiveness through routine management.

The second category refers to medical devices that should be controlled for their safety and effectiveness.

The third category refers to medical devices implanted in the human body to support and sustain life; which are potentially dangerous to the human body and must be strictly controlled for their safety and effectiveness.

医用设备的分类

医疗器械等级要求可分三类

第一类、指通过常规管理足以保证其安全性、有效性的医疗器械；

第二类是指对其安全性、有效性应当加以控制的医疗器械

第三类是指植入人体、用于支持和维持生命；对人体具有潜在危险且对其安全性、有效性必须严格控制的医疗器械

In China, CFDA has its own branches in each province and can issue certificates for medical equipment. Usually, the first and the second categories of equipment are applied for and tested at the CFDA branch of the province where the manufacturer is located. If the manufacturer is not located in China, the safety application is submitted to CFDA in Beijing or through the manufactures local China sales office in that province. The third category of equipment must be applied for, tested and obtained a certificate at the Beijing CFDA General Administration.

在中国，CFDA在每个省都有其分支机构，可以发放相应的医用设备的证书。通常，第一类，第二类设备在用户所在省的CFDA分支机构进行申请，测试。第三类设备则必须在北京CFDA总局申请，测试，并获得证书。

The power supply can be used as a component for any of the three categories of the complete medical equipment. The required standards are usually for safety (GB9706) and EMC standard (YY0505)

The current version of the Chinese medical general standard is GB9706.1-2007, which was implemented on July 1, 2008, (equivalent to IEC60601-1:1988+A1:1991+A2:1995 often referred to as the 2nd Edition). It is applicable to medical devices and not specific components that are part of a medical device such as a power supply.

According to the above, since the power supply cannot be approved to GB9706, the CFDA accepts the corresponding CB or other national test reports or certificates, such as CB, UL, TUV.

针对电源，由于它的通用性，是可以作为整机设备三类中的任何一类的配件，所要求的通常是安全（GB9706），EMC（YY0505）

GB9706：目前中国的医用通用标准的版本是： GB9706.1-2007，在2008年7月1号实施，（等同于 IEC60601-1：1988+A1：1991+A2：1995）

按照上述，由于中国电源不可以做GB9706，所以CFDA接受相应的CB或者其他国家的测试报告或证书，

如CB，UL， TUV。

At present, IEC60601-1 is already at Edition 3.1. If the power supply manufacturer provides a MOPP version of 3.1 it can be accepted by CFDA. However if it is MOOP then testing to MOPP (i.e. the 2nd Ed) is required. Therefore, customers sometimes ask power supply manufacturers to provide both IEC60601-1 Editions 2.0 and 3.1 test reports.

The current Medical EMC standard is YY0505-2012 Medical Electrical Equipment Part 1-2 "Safety General Requirements Parallel Standard: Electromagnetic Compatibility Requirements and Tests, issued on December 17, 2012, and implemented on January 1, 2014. It is equivalent to IEC60601 -1-2:2004.

The CFDA usually does not require the applicant to provide a test report for the power supply to YY0505, because this is a medical device or system requirement. However, customers usually require the power supply manufacturer to provide the corresponding test report. The test report according to IEC60601-1-2 Edition 2.1 is acceptable.

Since the IEC60601-1-2 EMC standard is currently at fourth Edition (IEC60601-1-2 2014, 4th ed.), the power supply should meet both the requirements of version 4.0 and the 2.1 Edition.

目前IEC60601-1 在国际上已经是3.1版，如果电源供应商提供3.1版的测试报告或者整数也是可以被CFDA接受的，但如果与IEC60601-1 2.0 版不同的地方是要求做测试的。这就是有时客户会要求电源供应商同时提供符合IEC60601-1 2.0版和3.1版测试报告的原因。

YY0505：目前的版本是YY0505-2012 医用电气设备第1-2部分“安全通用要求 并列标准：电磁兼容要求和试验， 于2012年12月17号发布，2014年1月1号实施，等同采用IEC60601-1-2：2004（2.1版），即IEC60601-1-2：2001+A1：2004

CFDA通常不要求申请者提供YY0505的测试报告，这个测试时随着整机一起作测试。但是客户通常会要求电源生产厂家提供相应的测试报告，按照IEC60601-1-2 2.1版的测试是可以被接受的。

同样，目前IEC60601-1-2 在国际上已经是第4版（IEC60601-1-2 2014，Edition 4），所以电源供应商的电源不光是要满足4.0版的要求，也要同时符合2.1版的要求，

If the power supply does not have a medical level test report such as CB, then the CFDA testing organization will test the power supply. At this time, the power supply manufacturer are required to provide the circuit diagram, critical components list, structure diagram of the main transformer, samples for the power supply and relevant certifications for key components.

如果电源没有取得如CB等医疗级别的认证，那么CFDA测试机构就要对电源作测试，这时电源通常会被要求提供电路图，关键安全件，主变压器的结构图，和关键元件的相关认证证书。

SUPERVISION

CFDA will conduct market surveillance and tests on medical devices sold in the market. This is in order to ensure that the medical devices sold in the market are continually in compliance of the medical standards. Mainly for the safety and proper operation of medical equipment, the compliance of EMC and important raw materials are checked.

Products not in compliance during the market surveillance process can be recalled. Therefore, it is very important for medical equipment manufacturer to maintain compliance of the product with the original application after obtaining medical registration.

监管

CFDA为了保证获得证书的医疗设备在市场销售时与当初做申请注册时的一致性，会随时对市场上销售的医用设备进行抽查，检测。主要针对医疗设备的安全性，EMC和重要原材料的一致性进行检查。我们已经看到在CFDA网站上有的产品被要求进行召回处理。所以医用设备在取得医疗的注册后，保持产品与当初申请的一致性是非常重要的。

As a key component, the model number of the power supply is required to be listed in the critical component list of the medical device.

Finally, all of SLPE's medical power supplies have been certified by UL, CB, and DEMKO, which customers can use to help their equipment obtain CFDA certification in China. These certificates are available on the SLPE website. If you have any questions, please refer to our sales office in Asia for support.

最后，SL的所有电源已经取得了UL，CB， DEMKO的医疗等级的证书，客户可以使用它们去帮助整机设备获得中国的CFDA认证，并且这些证书可以在SLPE的网站上获得。如有任何问题，请参考下方我司的亚洲地区的销售处获得支持。