

在美国如何查询这个类别是否可以不需要申请 510K 注册。

美国官网：<https://www.fda.gov/>

1. 首页下拉，Medical Device



2. 点击如下图



3. 在框中点击，输入查询内容



4.如输入 FMK，点击 Search:

Product Classification

FDA Home Medical Devices Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

[Learn More...](#)

FMK Search [Advanced Search](#)

5.查询结果如下：为 510(K) Exempt,说明不需要申请 510K。

Product Classification

FDA Home Medical Devices Databases

New Search [Back to Search Results](#)

Device	Lancet, Blood
Regulation Description	Manual surgical instrument for general use.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	FMK
Premarket Review	General Surgery Devices (DHT4A) General Surgery Devices (DHT4A)
Submission Type	510(K) Exempt
Regulation Number	878.4800
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Note: FDA has exempted almost all class I devices (with the exception of [reserved devices](#)) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with [21 CFR Parts 862-892](#). Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in [21 CFR Parts 862-892](#), a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the [Device Registration and Listing website](#) for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible



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