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

Food Drugs Medical Devices Radiation-Emitting Products

Vaccines, Blood, and Biologics Animal and Veterinary Cosmetics Tobacco Products

PRODUCTS WE REGULATE

## 2.点击如下图

## SEARCH MEDICAL DEVICE DATABASES



## 3.在框中点击,输入查询内容





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



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