Medical Device Exemptions 510(k) and GMP Requirements

Introduction

Following is a breakdown of 510(k) exempt and Good Manufacturing Practice (GMP)/Quality System exemptions listed by device class. All listed devices are 510(k) exempt unless further qualified by a footnote. Only devices annotated by (*) are also exempt from GMP except for general recordkeeping requirements and compliant files.

Class I Devices

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. Some 510(k) exemptions annotated with "\#\" are with certain limitations as noted in the footnotes. 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 by submitting Form FDA 2891, "Initial Registration of Device Establishment," and list the generic category or classification name of the device by submitting Form FDA 2892, "Device Listing."

IMPORTANT NOTE: Only the class I devices with an asterisk (*) are also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), **as long as the device is not labeled or otherwise represented as sterile.**

Class II Devices

The Food and Drug Administration (FDA) has also published a list of class II (special controls) devices (those devices are annotated as "(II)"), subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the Modernization Act. Class II devices are annotated "(II)". Please note that class II devices are NOT

exempt from GMP requirements.

Class I and Class II Exempt Devices

PART 862	Clinical chemistry and clinical toxicology devices
PART 864	Hematology and pathology devices
PART 866	Immunology and microbiology devices
PART 868	Anesthesiology devices
PART 870	Cardiovascular devices
PART 872	Dental devices
PART 874	Ear, nose, and throat devices
PART 876	Gastroenterology-urology devices
PART 878	General and plastic surgery devices
PART 880	General hospital and personal use devices
PART 882	Neurological devices
PART 884	Obstetrical and gynecological devices
PART 886	Ophthalmic devices
PART 888	Orthopedic devices
PART 890	Physical medicine devices
PART 892	Radiology devices

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