EBOOK

A STEP-BY-STEP GUIDE TO DETERMINE HOW YOUR MEDICAL DEVICE WILL BE CLASSIFIED

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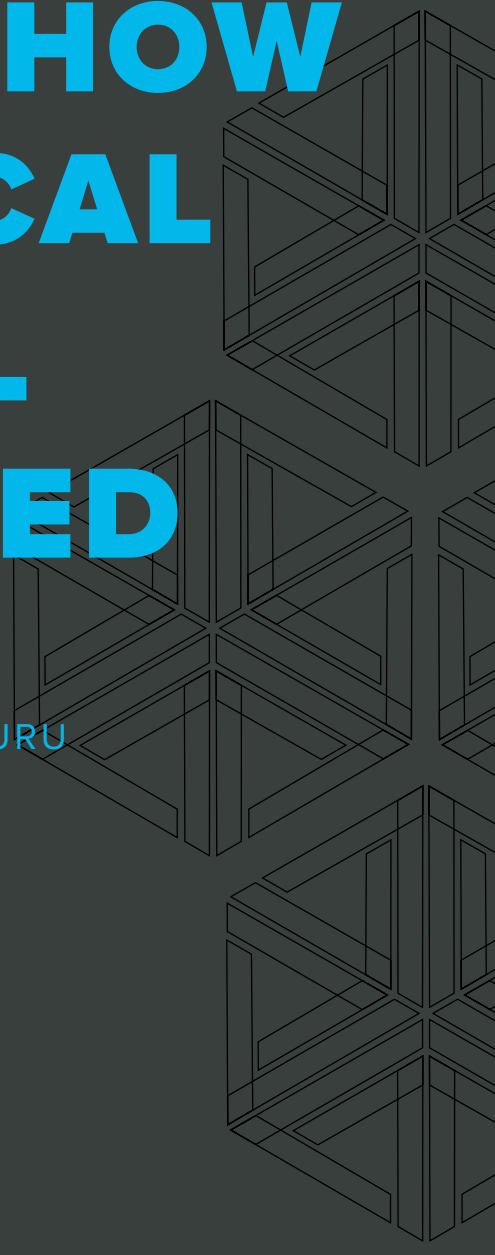

greenlight guru

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TABLE OF CONTENTS

3. Regulatory Classification 101
5. Medical Device Regulatory Classification in the U.S.
11. Medical Device Classification in Europe
14. Medical Device Classification in Canada
18. Update to Health Canada Regulations: MDSAP

A STEP-BY-STEP GUIDE TO DETERMINE HOW YOUR MEDICAL DEVICE WILL BE CLASSIFIED

What I am about to share with you is a guide to medical device regulatory classification.

In this guide, I will provide you with a step-by-step approach for determining how your medical device will be classified by U.S. FDA, the European Commission, and Health Canada. Getting a basic understanding of regulatory product classification will be invaluable to your efforts to bring new products to market.

REGULATORY CLASSIFICATION 101

Each regulatory agency has defined several different classifications for medical devices.

The classifications are, for the most part or as a general rule, related to the perceived risk of the product type.

Medical device manufacturers selling internationally need to familiarize themselves with the applicable regulations of those markets. This is easier said than done and can be a challenge for most manufacturers. The US has its set of rules, while Canada adheres to another, and Europe another one still.

Fortunately, there are many parallels between international medical device regulations and standards. This guide is designed to show you how to classify your device in different markets around the world.

WHY DOES REGULATORY CLASSIFICATION EVEN MATTER?

Knowing how your medical device is classified matters for the following reasons:

1. Product classification will determine what you have to do before you can sell your product.
2. Product classification will help you establish requirements during the product development phase, specifically design controls.
3. Product classification is an important component in determining how much it will cost to bring your device to market and give you some idea of how long it will take.

Because of this, I'm going to provide you with a little bit of guidance to better understand what to do and how to do it.

Note, the information I'm about to provide is intended to help educate you on medical device regulatory classification and what is required for your medical device.

The following content is not a comprehensive guide to regulatory submissions, yet should give you some basic guidance and direction on identifying how to establish path to market.

I'll stick to the *big 3* you should know when it comes to medical device classification:

1. U.S. Food & Drug Administration, Center for Devices & Radiological Health (FDA CDRH)
2. European Commission
3. Health Canada

MEDICAL DEVICE REGULATORY CLASSIFICATION IN THE U.S

U.S. FOOD & DRUG ADMINISTRATION (FDA)

In the United States, medical devices are regulated by the Food & Drug Administration, or FDA. The specific branch within the FDA is the Center for Devices & Radiological Health (CDRH).

The mission of CDRH is to protect and promote public health. In other words, ensure medical devices are safe. In the U.S., medical devices are either Class I, Class II, or Class III. The FDA CDRH classification is based primarily on risk the medical device poses.

Class I medical devices are generally deemed low risk and Class III medical devices are seen as the highest risk. The types of controls required is dependent on your product's classification.

Classification is directly related to intended use and indications for use. The distinction between these terms is a bit confusing.

- **Intended Use** is the general purpose of the medical device or its function (what you "claim" the medical device does).
- **Indications for Use** describe the disease or condition the medical device will diagnose, treat, prevent, cure, or mitigate, including a description of the target patient population.

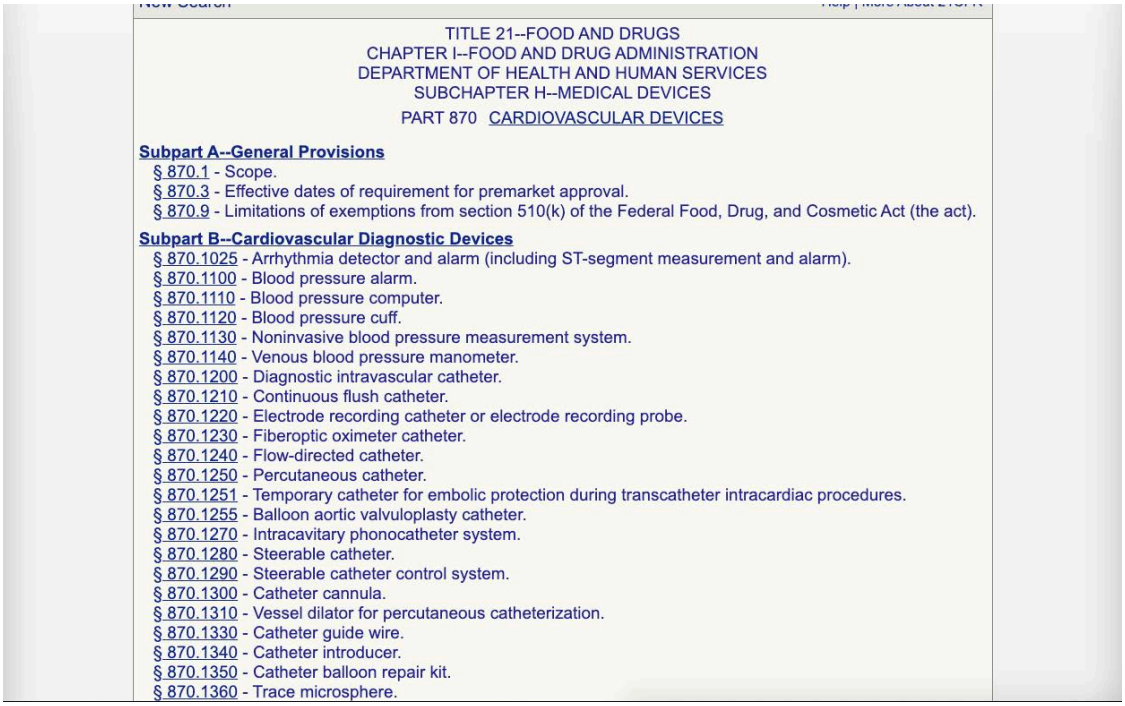
Keep this in mind. The intended use and indications for use of your medical device express the reason why you had this idea for a new medical device.

HOW TO FIND THE APPLICABLE FDA REGULATIONS FOR YOUR MEDICAL DEVICE

Once you define intended use and indications for use, now you need to find the possible regulations and product codes. Tracking down regulatory classification for your product via FDA takes a little bit of time and perseverance.

Without boring you with too many details, FDA has established several general categories based on the medical specialty in CFR Title 21 - Food and Drugs: Parts 862 to 892.

When you find the possible categories and click on the FDA regulation number, the list of possibilities suddenly seems endless. Here is a partial view of the options for Part 870 Cardiovascular Devices:



TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 870 CARDIOVASCULAR DEVICES

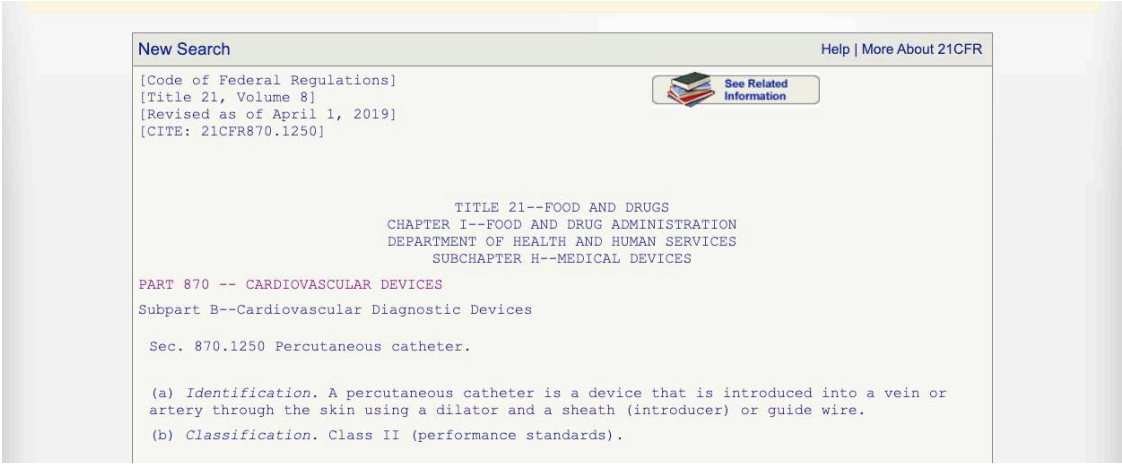
Subpart A--General Provisions
§ 870.1 - Scope.
§ 870.3 - Effective dates of requirement for premarket approval.
§ 870.9 - Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B--Cardiovascular Diagnostic Devices
§ 870.1025 - Arrhythmia detector and alarm (including ST-segment measurement and alarm).
§ 870.1100 - Blood pressure alarm.
§ 870.1110 - Blood pressure computer.
§ 870.1120 - Blood pressure cuff.
§ 870.1130 - Noninvasive blood pressure measurement system.
§ 870.1140 - Venous blood pressure manometer.
§ 870.1200 - Diagnostic intravascular catheter.
§ 870.1210 - Continuous flush catheter.
§ 870.1220 - Electrode recording catheter or electrode recording probe.
§ 870.1230 - Fiberoptic oximeter catheter.
§ 870.1240 - Flow-directed catheter.
§ 870.1250 - Percutaneous catheter.
§ 870.1251 - Temporary catheter for embolic protection during transcatheter intracardiac procedures.
§ 870.1255 - Balloon aortic valvuloplasty catheter.
§ 870.1270 - Intracavitary phonocatheter system.
§ 870.1280 - Steerable catheter.
§ 870.1290 - Steerable catheter control system.
§ 870.1300 - Catheter cannula.
§ 870.1310 - Vessel dilator for percutaneous catheterization.
§ 870.1330 - Catheter guide wire.
§ 870.1340 - Catheter introducer.
§ 870.1350 - Catheter balloon repair kit.
§ 870.1360 - Trace microsphere.

This can be frustrating and overwhelming.

When you find a regulation that appears to be a possible fit, you can click on the link and get more details to make a determination.

For example, if I think my device fits in 870.1250 Percutaneous catheter, I click the link and get this information:



New Search | Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2019]
[CITE: 21CFR870.1250]

See Related Information

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 870 -- CARDIOVASCULAR DEVICES

Subpart B--Cardiovascular Diagnostic Devices

Sec. 870.1250 Percutaneous catheter.

(a) *Identification.* A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.

(b) *Classification.* Class II (performance standards).

The details provided give me some idea if my Intended use and indications for use align with this specific regulation. I also discover the FDA device classification.

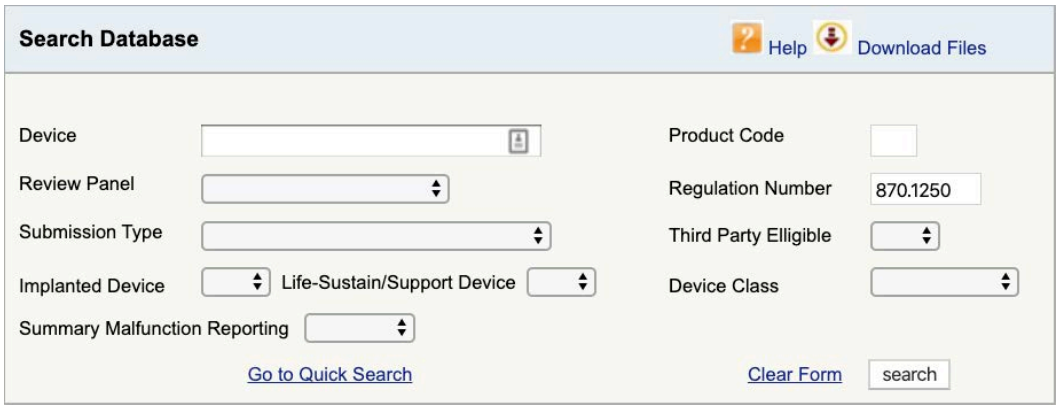
In this example, I learn that my product is a Class II medical device (performance standards), which means I will need to submit a 510(k) to FDA prior to getting market clearance. I share more about types of FDA submissions further on in this guide.

NEXT – FIND THE PRODUCT CODES APPLICABLE TO YOUR DEVICE

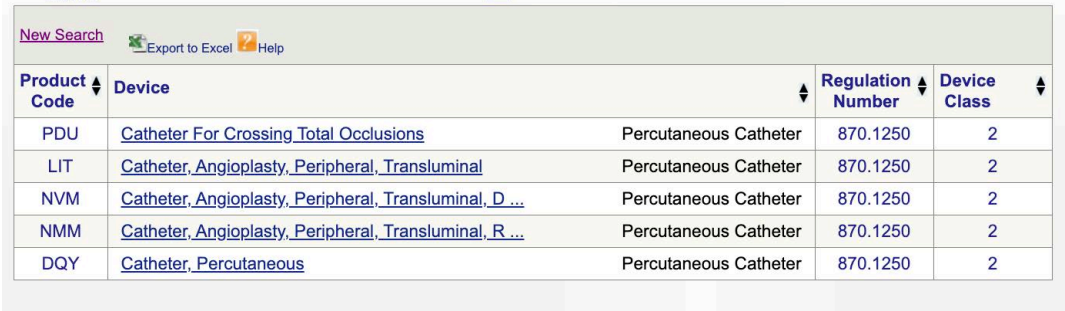
Finding the applicable regulation for you medical device and classification is the first part. Now you need to find the applicable product codes.

Here's how:

> Go to the FDA Product Classification Database and type in the regulation number you found. If you find more than one possibility, then you will need to repeat this process for each.



> When you click "search" you will get a list of possible product codes.



Product Code	Device		Regulation Number	Device Class
PDU	Catheter For Crossing Total Occlusions	Percutaneous Catheter	870.1250	2
LIT	Catheter, Angioplasty, Peripheral, Transluminal	Percutaneous Catheter	870.1250	2
NVM	Catheter, Angioplasty, Peripheral, Transluminal, D ...	Percutaneous Catheter	870.1250	2
NMM	Catheter, Angioplasty, Peripheral, Transluminal, R ...	Percutaneous Catheter	870.1250	2
DQY	Catheter, Percutaneous	Percutaneous Catheter	870.1250	2

> You can then review each individual code to determine the best option for your product by clicking on each code.

DETERMINING YOUR PATH TO MARKET IN THE U.S.

Knowing the applicable regulation and product code (as described above) is necessary for you to determine the classification of your medical device. Once you have this information, you will now be able to determine the pathway for getting your product registered with FDA.

FDA defines three regulatory controls for each medical device class:

- Class I medical device (low to moderate risk): General Controls
- Class II medical device (moderate to high risk): General Controls and Special Controls
- Class III medical device (high risk): General Controls and Premarket Approval (PMA)

Let me boil it down to this:

If you find your product is "exempt," then only general controls apply and no formal FDA submission is required. You do, however, need to register your establishment with FDA and then list the product.

If you find your product requires special controls, this means you will have to prepare a 510(k) submission to FDA and receive clearance before going to market. After that, you need to register your establishment and list the product.

If you find your product requires premarket approval, this means you will have to follow the FDA PMA process to receive approval before going to market.

MEDICAL DEVICE CLASSIFICATION IN EUROPE

EUROPEAN COMMISSION

The regulations for a medical device in European Union (EU) are established through the Medical Device Directives by the European Commission (EC).

The path to market in Europe is to obtain a CE marking.

To figure out what is required to obtain a CE marking your medical device, you must first determine the EU classification of your medical device. The European Union's medical device regulation (EU MDR) includes the necessary information to determine your device class.

EU MDR 2017/745 amends Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. EU MDR will become the mandatory regulation for medical devices starting in May 2020.

You will need to determine if your medical device is:

- Non-Invasive
    - Any device which does not penetrate the body through an orifice or the surface of the body. These devices are typically Class I; however certain rules and exceptions apply that could make them Class II or higher.
- Invasive
    - Any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
- Active
    - Any device whose operation depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy.

For each of the broad categories, there are certain rules which apply, outlined in Annex VIII of the new medical device regulation. These categories coupled with the duration for use make determining classification fairly straightforward.

For example, a device in continuous use for under 60 minutes is considered transient duration, 60 minutes to 30 days is considered short-term, and over 30 days is considered long-term.

With that in mind, to determine the EU classification of your device, we can use the percutaneous catheter example used earlier in this guide for FDA classification.

Let's say I determine my medical device fits into the "invasive" category. This narrows my search down to Rules 5, 6, 7, and 8.

I can then narrow the rules down further since I know my medical device is short-term because it is used for a period greater than 24 hours and less than 30 days.

From there, I am able to determine that Rule 7 is most applicable to the classification of my device.

5.3. Rule 7

All surgically invasive devices intended for short-term use are classified as class IIa unless they:

— are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;

— are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;

— are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;

— have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;

— are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or

— are intended to administer medicines, in which case they are classified as class IIb.

EU MDR 2017/745 Annex VIII 5.3

Since my percutaneous catheter will administer medicines, I can confirm that my medical device is considered a Class IIb medical device in the European marketplace.

DETERMINING YOUR PATH TO MARKET IN EUROPE

The European Union has a similar product classification system as the U.S.:

- Class I
- Class IIa
- Class IIb
- Class III

In all cases for medical devices to be sold in the European Union, technical documentation is a required step in the process of obtaining CE Marking. All medical device classes in the EU require working with a Notified Body, except for those which are Class I and can be self-certified.

Companies will also need to work with an Authorized Representative to take care of product registration in Europe. The article 11 Top Questions on EC Authorized Representatives can help to provide further clarification on how to achieve medical device classification in Europe.

MEDICAL DEVICE CLASSIFICATION IN CANADA

Health Canada Santé Canada

HEALTH CANADA

The medical devices regulations in Canada are established by the Government of Canada and regulated by Health Canada.

Like the U.S. and EU, to sell into the Canadian marketplace, you must first determine the medical device classification under Canada's regulation.

Similar to the requirements outlined in EU MDR, Health Canada provides a fairly straightforward and easy to follow Guidance on the Risk based Classification System for Non-In Vitro Diagnostic Devices for medical device manufacturers to use when selling into this market.

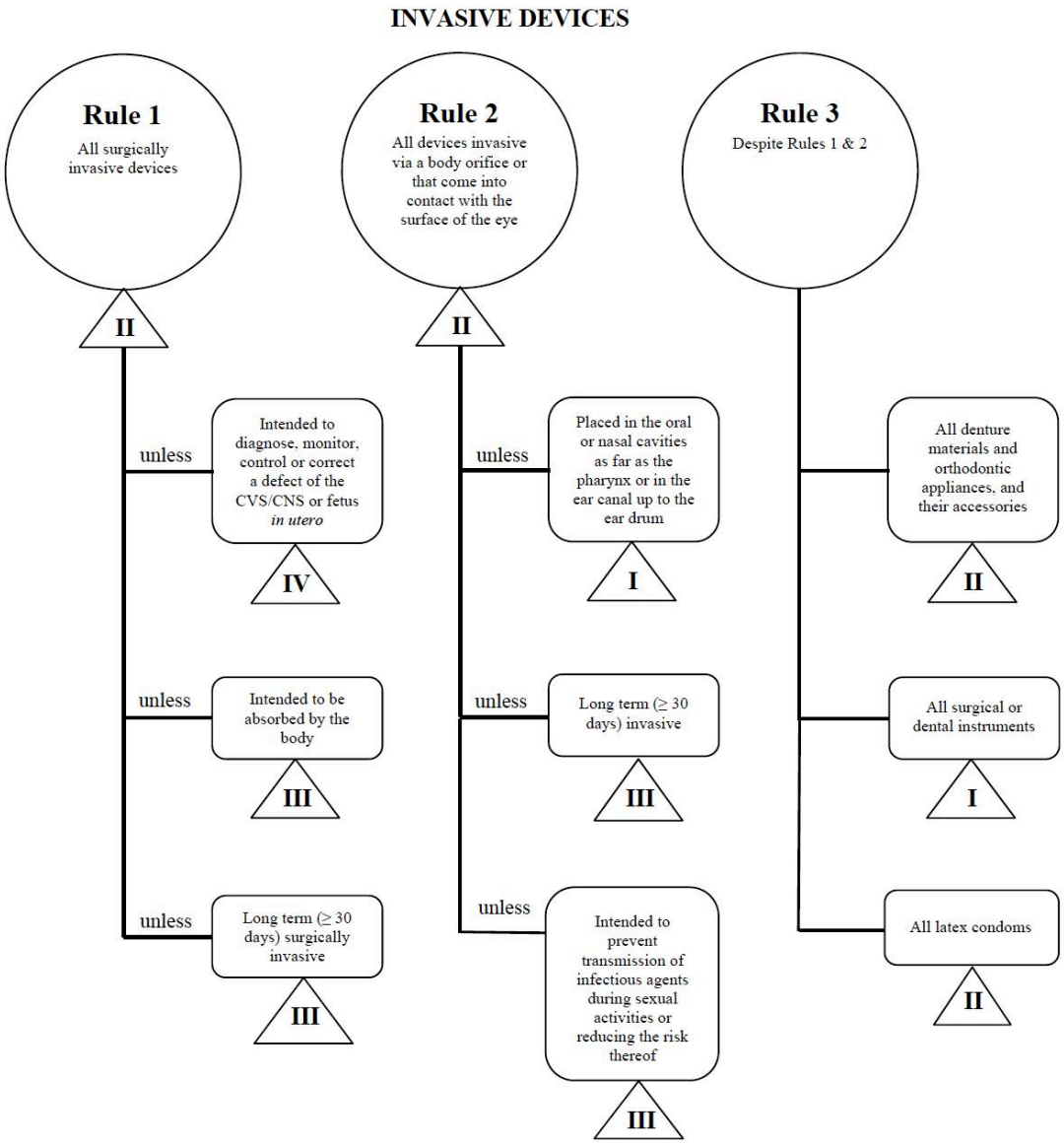
Health Canada defines four groups of non-in vitro diagnostic medical devices:

- Invasive Devices (Rules 1 - 3)
- Non-Invasive Devices (Rules 4 - 7)
- Active Devices (Rules 8 - 12)
- Special Rules (Rules 13 - 16)

For each of the broad categories, there are a set of rules which apply. These rules are what manufacturers should follow in order to determine the risk classification of their device.

I'll use the percutaneous catheter example once more in the case of marketing such a device in Canada.

I determine my medical device fits into the "invasive" category, narrowing my search down to Rules 1, 2, and 3.



Guidance on the Risk based Classification System for Non-In Vitro Diagnostic Devices

After reviewing the options, I determine that Rule 1 applies.

Based on my intended use, my medical device is considered Class II in Canada.

DETERMINING YOUR PATH TO MARKET IN CANADA

There are four levels of medical device classifications in Canada:

- Class I
- Class II
- Class III
- Class IV

Prior to going to market in Canada, you must first apply for a medical device license. Class I medical devices do not require a license. Manufacturers can reference the Health Canada guidance document, which walks you through this process.

Manufacturers of Class III and Class IV medical devices can receive their license by submitting a premarket application, in either the ToC or Health Canada formats, for entering the Canadian market.

You will also need to obtain ISO 13485 certification with MDSAP.

UPDATE TO HEALTH CANADA REGULATIONS: MDSAP

As of January 2019, all medical device manufacturers selling Class II medical devices and higher to the Canadian market need to be part of the Medical Device Single Audit Programme (MDSAP).

These manufacturers must undergo and pass a full audit of their quality management system (QMS) through the programme in Canada. There are currently 6 regions around the world that participate in MDSAP, including Canada, U.S., Japan, Brazil, and Australia.

Aside from those manufacturers required by Health Canada to participate in the program, participation in MDSAP is optional for manufacturers.

To gain MDSAP certification, medical device manufacturers must complete the following three steps:

1. Application and review
2. Off-site documentation audit
3. On-site audit

Device makers selling into Canada will be subjected to annual reviews, with a recertification audit every third year. Compliance with the Medical Device Single Audit Programme is based on meeting the guidelines from the ISO 13485 standard on quality management systems for medical devices.

We recommend training your product and quality and regulatory teams in the applicable MDSAP requirements to streamline your application.

Our free gap assessment tool for MDSAP and ISO 13485 helps device makers assess the QMS guidelines from the ISO standard alongside the requirements of Health Canada auditing organizations (AO) and other regions participating in the programme.

FINAL THOUGHTS

You now have the information and resources you need to determine your medical device classification and path to market in the three of the biggest marketplaces around the world.

Regardless of the classification of your device, it's imperative that you follow the regulatory guidelines that apply in each market. Meeting compliance is a key aspect of quality management that will ultimately decide the fate of your device and company as a whole.

At Greenlight Guru, we value the importance of medical device quality management (MDQMS). Our MDQMS software is the only solution in the world designed specifically for medical devices. It's aligned with the latest industry standard best practices for managing product design controls and risk, as well as change control activities and other quality events, providing full traceability throughout the lifecycle of your medical device.

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