How is My Medical Device Classified: Case Study

Slide 1

Hello, my name is Commander Kimberly Piermatteo of the United States Public Health Service and I am a Consumer Safety Officer within the Center for Devices and Radiological Health's Division of Industry and Consumer Education at FDA. Welcome to CDRH learn, CDRH's resource for multimedia industry education. Within this CDRH Learn module, I will provide you with an illustrative example of how you can determine the class of a medical device using three different determination methods. Determining how a medical device is classified is instrumental in understanding and identifying the appropriate regulatory requirements for a device.

Slide 2

This module is a companion to the CDRH Learn module titled "How is my medical device classified?" If you have not done so already, please review this module first before proceeding to watch this case study.

Slide 3

Before I begin the case study, I'd like to review a few points made in the companion module. First, medical devices are classified based on risk. Medical devices may be classified as Class I, Class II or Class III. Second, the risk of the device determines the extent of regulatory controls. And lastly, there may be an applicable premarket submission type for a device unless exempt. The table displayed on this slide was discussed in detail within the companion module, and I have provided it again here as it provides an overview of the medical device classes and their applicable regulatory requirements.

Slide 4

The following learning objectives will be addressed within this case study. I will describe three different classification determination methods. The methods are, one, search for an appropriate product classification, two, search for a similar device by clearance or approval, and three, search for a similar device by device listing.

Slide 5

For this case study, I'm going to use a traction device as my example. The intended use of this traction device is to treat low back pain through intermittent and static traction.

Slide 6

As I mentioned when determining a device's product classification, there are three methods that I recommend. The first is to directly search for the appropriate product classification. I'll refer to this as method 1 and this is the most common method used. A second method, or method 2, is to search for a similar device by its clearance or approval. And lastly, method 3 is to search for a similar device by device listing. I'm going to walk through how to conduct each of these search methods over the next several slides.

Slide 7

First, we will look at method 1.

Slide 8

To search for an applicable product classification, I will be searching the FDA's public product classification database. A screen shot of the product classification database is provided on this slide. You

may search the various fields provided; however, I recommend you go to the quick search feature which is circled in red on this slide. From the quick search, you can search using a key word.

Slide 9

For this example, I'm going to search using the key word "traction". I would enter the key word in the search field and select search. I could conduct multiple searches using other words, but I feel this one most appropriately describes the example device. When searching the product classification database, remember to conduct multiple searches using a variety of key terms so that you ensure you capture as many potentially related product classifications which you can then narrow down. Keep in mind spelling matters and I suggest you avoid plurals and don't be too specific as this will limit your results.

Slide 10

On this slide, you will see a screen shot of my quick search results using the key word "traction". The default display setting for this database is 10 results, so if you wish to expand the number of results displayed per page, you can select the drop down circled in blue, at the top right of the screen shot, to change the number of results displayed per page. For this example, I have chosen to display up to 100 results. As noted by the red circle, 11 results are now displayed. I could review each product classification to determine if it applies to my traction device, or I could further define the intended use of the traction device so that I can narrow down the results even faster.

For this example, I'm going to clarify the intended use of the traction device to indicate that it is a powered traction device.

Slide 11

Now looking at the results, I see there is a product classification for a non-powered traction apparatus, highlighted in yellow on the slide, but then there is a more applicable powered traction equipment highlighted in green below.

Slide 12

Therefore, the ITH product code looks to be more applicable to my powered traction device. I'm going to take a further look at this product code to confirm whether the ITH product code appropriately describes my device.

Slide 13

This next slide displays a screen shot of the product classification information for the ITH product code. At this point, I want to ensure this product code and the associated regulation number, 21 CFR or code of federal regulations, 890.5900, appropriately describes my powered traction device.

Slide 14

Therefore, I'm going to select the hyperlink for the regulation number to further review the description. I have highlighted the regulation number I'm going to select in the black box and orange arrow on this slide.

Slide 15

The regulation description states – "Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body." Based on this regulation description, I believe

this would be the most appropriate regulation for the traction device in my example, as well as the ITH product code seems to be the most appropriate.

Slide 16

Going back to the screen shot for the ITH product code in the public Product Classification database, I can then determine what regulatory requirements apply to this powered traction device. I can see on the screen that the submission type for a powered traction equipment device is 510(k), which is highlighted in yellow on this slide, which means I would need to obtain 510(k) clearance prior to marketing this device. Additionally, this device type is considered to be class two, which means general controls apply as well. If there were any special controls for this device type, I would have been able to review them as part of the regulation description.

Slide 17

Next, I'm going to discuss method 2, which is to search for a similar device by its clearance or approval. Using method 2, I will demonstrate that I will come to the same conclusion as Method 1 by determining that the ITH product code is the most appropriate for a powered traction device.

Slide 18

Using method 2, I can search for a similar device by 510(k) clearance or premarket approval. For this method it is important to note, I would only be able to search for devices which have received 510(k) clearance or premarket approval. Since most Class I devices are exempt from 510(k), I would not be able to find them by using this method. One note I'd like to make is regarding De Novo applications. The De Novo pathway provides a possible route to classify novel devices of low to moderate risk. If you think a similar device to your own was the first new, novel device type, then this first marketing authorization would not be found in the 510(k) clearance database.

You would need to search the De Novo database to find this first classified device under the newly created regulation. To find a device that has been cleared under 510(k), or approved under a Premarket Approval Application, or a PMA, you can search the respective public databases using the hyperlinks provided on this slide.

The powered traction device, in this example, is not life supporting or life sustaining, so I can presume that it is not likely considered to be high risk, so I wouldn't need to search the PMA database for a similar device. Additionally, I do not believe powered traction devices are new or novel, therefore, I'm not going to search the De Novo database either. I'm going to proceed and search the 510(k) clearance database to see if I can find the similar device I'm looking for.

Slide 19

On this slide, I've provided a screen shot of the public 510(k) clearance database. The Advanced Search is the default, but there is also a Quick Search available which is circled in red at the bottom of the screen shot. Within the Advanced Search, there are many fields you may search, but I find the Quick Search to be more helpful in identifying a wide range of results which I can then narrow down myself. In order to steer this example even further, I'm going to state that I'm looking for a similar device called the Digit-trac 930.

So, let's take a closer look and see if this similar device has a 510(k) clearance which I can review, and then determine how it has been classified to ultimately determine if the same classification applies to my traction device.

Slide 20
Within the Quick Search of the 510(k) clearance database, which is pictured on this slide, I still want to keep my search broad to capture as many results as possible, so I'm going to enter the word "traction" in the search box.

Slide 21
The screen shot provided on this slide shows that by searching the key word "traction", I obtained 93 results, which I've circled in red at the top left and the first 14 results are displayed. Note, I conducted this search in July of 2019, therefore, if you were to conduct a similar search after this date, you may obtain different results if a more recent device received 510(k) clearance. For this example, I said I'm looking for the similar device called the Digit-trac 930.

After reviewing the first few results, I was able to find a device called the "traction system, digit-trac 930", as I've highlighted in green.

Slide 22
In order to review more information about this 510(k) clearance, I could either select the device name or the 510(k) number hyperlink. I'm going to select the 510(k) number K052453 as identified by the red arrow.

Slide 23
This slide shows detailed information about the 510(k) that I selected for the Digit-trac 930. I can see this type of device was cleared under the regulation number 21 CFR 890.5900 and product code ITH, as highlighted in red. If I want, I can review more information about the regulation and product code by selecting the respective hyperlinks which will take me to the product classification database results that I viewed previously under method 1.

After reviewing this information, I could then determine if this regulation and product code appropriately describe my traction device. And then I could determine what the regulatory requirements are, such as for the ITH product code a 510(k) clearance is required.

Slide 24
I could also review the 510(k) summary for the digit-trac 930 to obtain more information on this device's intended use, to ensure this is the similar device I was originally looking for. A hyperlink to the 510(k) summary is highlighted in green on this slide.

Slide 25
The last method I recommend for determining the appropriate product classification for a device is method 3, which is to search for a similar device by device listing. This method is useful because establishment registration and device listing are a general control, which means all medical device manufacturers currently marketing a device in the U.S. must be registered and their devices listed. So, if I know of a similar device currently being marketed, I can search for it by its listing and see if the same product classification then applies to my example device.

Slide 26
A screen shot of the FDA's public Establishment Registration and Device Listing database is provided on this slide. Again, the default is the Advanced Search which allows me to search by establishment or

trade name, or I could search by key word, again using the Quick Search. I'm going to use the Quick Search.

Slide 27

This slide shows the Quick Search for the Establishment Registration and Device Listing database. The Quick Search for this database is very similar to the Quick Searches in the other public databases I used for the previous methods. I'm going to also search using the key word "traction", as circled in red on this slide, to see what device listings I can find.

Slide 28

By searching using the key word "traction", I obtained 22 results, as circled in blue on this slide. Remember, I'm looking for the similar device called the digit-trac 930, so if I review my results, I eventually see that there is a digit-trac 930 powered traction equipment listed by the company Ever Prosperous instrument, incorporated, which I've highlighted in red.

Slide 29

If I select the establishment name, this will take me to information about the establishment's registration. But I want to know more about the device and see how it is classified, so I'm going to select the product name, as indicated by the green arrow on this slide.

Slide 30

Under this device listing, I can review information about how this device has been classified to determine if the same classification applies to my device example. Highlighted in red, I can see the digit-trac 930 falls under the product code ITH, it is Class II, and the applicable regulation is 21 CFR 890.5900. This is the same classification information I was able to find by searching the two previous methods. If I want to review more details about this device type and classification I could, again, select the hyperlink to the ITH product code or hyperlink to the regulation number. I could also select the 510(k) number, which is highlighted in yellow on this slide, and it will take me to the 510(k) clearance database, where I could review the 510(k) summary for this device as well.

Slide 31

To conclude this case study example, the table provided on this slide summarizes the results of the various searches I conducted using methods 1, 2 and 3. By using all three methods, I was able to come to the same conclusion regarding the appropriate product classification for my powered traction device. For this example, I can conclude that the appropriate class for a powered traction device, which is intended to treat low back pain through intermittent and static traction, is Class II, and must comply with general controls. The appropriate regulation number is 21 CFR 890.5900, the product code is ITH, and lastly, a 510(k) clearance is required prior to marketing this device.

Slide 32

In summary, within this module, I discussed three different methods which are available to help you determine how your medical device may be classified by the FDA. Once you know how your device is classified, you can then identify the applicable regulatory requirements for your device.

Slide 33

Additional resources and links are provided on this slide. I will not cover them in detail, but they are listed for your reference, as needed.

Slide 34

CDRH provides multiple opportunities for industry education. On this slide, I have provided you links to CDRH Learn, which consists of numerous learning modules covering a wide range of medical device topics; as well as Device Advice, which is a text-based resource, and lastly, you may contact the Division of Industry and Consumer Education, or DICE, by phone or email with questions.

Slide 35

My call to action for you is to conduct multiple searches in each of the FDA's public databases that I discussed in this module. By conducting different searches in each of these databases, you will be able to cross-check your results, and I hope you will feel more confident when it comes to identifying the most appropriate product classification for your device. Thank you for watching and I hope you found this module to be informative.

****