Chapter 11

Why Form 3429 is Needed

March 2016

CDRH seems determined to abandon the CQ, despite objections raised by AdvaMed, me, and perhaps others. The argument by CDRH that Form 3429 is unnecessary because there are alternative methods for arriving at the classification ignores the facts. In my opinion, a properly constructed CQ is the simplest and quickest way to determine the appropriate class for a device. Anyone knowledgeable about the device and familiar with the intent of the questions can complete the Form and determine the proper classification of a device in just a few minutes.

From my viewpoint, it is essential that CDRH adopt a properly constructed CQ. The revisions of July 2012 essentially destroyed the usefulness of the Form, and my Citizen Petition FDA-2014-P-0290 would have restored it. CDRH needs a properly constructed CQ, as the one used from 1997 (or earlier) contained a serious error which directed some devices into Class III which didn't belong there. This was a trap for anyone petitioning to have a device downclassified from Class III. And the revision of July 2012 is unsatisfactory because it doesn't lead to a conclusion about the appropriate class for any device. (I'm getting tired of having to repeat this over and over; you, poor reader, must be weary too. But I'll keep repeating it until somebody at CDRH takes their head out of the sand and does something to rectify the situation.)

CDRH has not yet admitted that this error was a real problem – they used the fallacious argument that the CQ contained "extraneous information" which was "confusing" to some.

Two Examples to Illustrate Why Form 3429 is Needed

Example 1: In Chapter 1, I discussed the recommendations of the Neurological Devices Panel at their meeting on February 10, 2012. The physician members of the Panel were nearly unanimous in their recommendation that Cranial Electrotherapy Stimulators should be in Class III for the three indications for use (anxiety, insomnia, and depression). When she was polled, the Patient Representative, Michelle Carras, offered the opinion that the devices in question do not qualify for Class III. See page 6 for her full statement. The Industry Representative agreed with her.

Clearly, the majority of the Panel voted for Class III without realizing the conditions to be satisfied in the definition of Class III.

IF A PROPERLY CONSTRUCTED CLASSIFICATION QUESTIONNAIRE HAD BEEN USED BY THE PANEL, THEY PROBABLY WOULD NOT HAVE RECOMMENDED CLASS III.

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Example 2: On April 30, 2015, the Ear, Nose and Throat Devices Panel met to discuss the classification of eight hearing protector devices which had never been classified.

The products which were discussed at the meeting are listed below with their respective Product Codes:

EWD – hearing protector (insert) devices
EWE – circumaural hearing protector devices
LRA – tactile hearing aids
LFA – speech training aids (battery-operated or non-patient contact)
LEZ – speech training aids (AC-powered and patient contact)
LXV – vestibular analysis devices
MJV – middle ear inflation device
LFB – nasal septal button

Marjorie Shulman modified her presentation on classification and reclassification for this meeting. It included the logic diagram in the PREVIUOS chapter (Figure 10.1). She did not mention the Classification Questionnaire; it was never mentioned during the entire meeting.

It seems strange to me that these devices, all considered to be pre-amendments devices, with many of them allowed on the market since the late 1970s under Section 510(k), had never been classified. I suppose this is an example of something slipping through the cracks.

The FDA expended considerable resources to prepare materials[1] associated with the meeting. A total of 24 items appear in the list of FDA-generated materials for the meeting. These include the Roster and Agenda, the 24-hour preliminary transcript and the meeting transcript. In addition, there were executive summaries for each device and a list of questions for each device.

The Panel spent most of the day discussing these devices. Why weren't these devices classified long ago? This is unclear.

http://www.fda.gov/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee/ucm443957.htm

April 30, 2015: Meeting Materials FDA Generated

- Agenda: April 30 2015 (PDF - 713KB)
- Roster: April 30, 2015 (PDF - 116KB)
- Regulatory Reference Sheet: April 30 2015 (PDF - 64KB)
- FDA Executive Summary EWD-EWE: April 30 2015 (PDF - 180KB)
- Panel Questions EWD-EWE Hearing Protector Devices: April 30 2015 (PDF - 22KB)
- Executive Summary LRA: April 30 2015 (PDF - 99KB)
- Panel Questions LRA Tactile Hearing Aids: April 30 2015 (PDF - 33KB)
- Executive Summary LFA-LEZ: April 30 2015 (PDF - 120KB)
- Panel Questions LFA-LEZ Speech Training Aids: April 30 2015 (PDF - 34KB)
- Executive Summary LXV: April 30 2015 (PDF - 160KB)
- Panel Questions LXV Vestibular Device: April 30 2015 (PDF - 29KB)
- Executive Summary MJV: April 30 2015 (PDF - 74KB)
- Panel Questions MJV Middle Ear Inflation: April 30 2015 (PDF - 20KB)
- Executive Summary LFB: April 30 2015 (PDF - 92KB)
- Panel Questions LFB Nasal Septal Button: April 30 2015 (PDF - 29KB)
- Presentation: Device Classification (PDF - 379KB)
- Presentation: Classification of Devices Under Product Codes EWD- EWE Hearing Protector (PDF - 254KB)
- Presentation: Classification of Tactile Hearing Aids Under Product Code “LRA” (PDF - 59KB)
- Presentation: Classification of Speech Training Aids LFA-LEZ (PDF - 63KB)
- Presentation: Classification of Vestibular Analysis Devices under Product Code “LXV” (PDF - 57KB)
- Presentation: Classification of Middle Ear Inflation Devices under Product Code “MJV” (PDF - 108KB)
- Presentation: Classification of Nasal Septal Button Devices under Product Code “LFB” (PDF - 428KB)
- 24 Hour Summary: April 30, 2015 (PDF - 372KB)
- Transcript: April 30, 2015 (PDF - 584KB)

If the Panel had been polled to answer the questions in properly-constructed Classification Questionnaire, I think it is reasonable to expect that they could have completed their work in far less time and with greater confidence.

The saga continues in Chapter 12.

END NOTES FOR CHAPTER 11

[1] The list of 24 items can be viewed at http://www.fda.gov/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee/ucm443957.htm. One can view the contents of each of the items by clicking on the item.