Chapter 12

Proposed Fix for Form 3429 - CDRH Proposes to Drop the Form

February – May 2014

Tired of waiting for CDRH to acknowledge the damage done to the Classification Questionnaire (CQ) when they deleted row 4 and column 3 in July 2012, I decided to take the initiative and suggest a fix for the problem.

CDRH had presented a few versions of their Classification Logic diagram at Panel meetings in recent years. Of course, a classification logic diagram is intimately related to the Classification Questionnaire because both are based upon the legal definitions of the three device classes. As we saw in Chapter 3, the CQ had deviated from the ideal for years before I identified the logical error. Figure 12.1 conforms to the definitions of the three device classes.

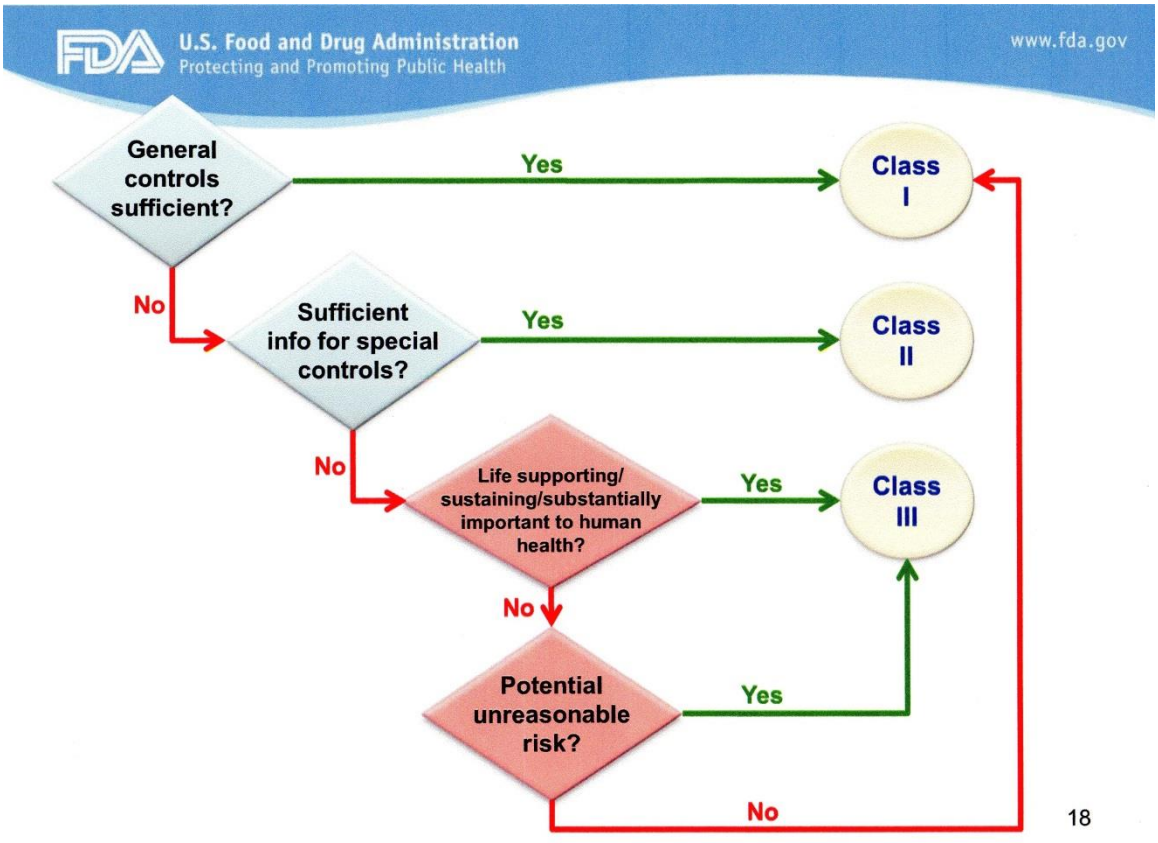

Figure 12.1 Classification Logic Diagram

Citizen Petition to Fix Form 3429

Figure 12.1 is the logic diagram presented at the Orthopaedic and Rehabilitation Devices Panel meeting on February 21, 2014[1]. I believe it satisfies all the criteria of the Class definitions.

I created another Citizen Petition. This Petition requested the Commissioner to revise Form 3429 to fix the problem created by the 2012 revision by CDRH. Figure 12.2 shows my proposed revision of Form 3429 (Exhibit A in the petition). The petition was filed on March 6, 2014 as Docket Number Docket No. FDA-2014-0283.

In addition to making changes to ensure that the Form accurately reflects the definitions of the classes, I suggested the addition of a version number to explicitly identify the version without having to consider the effective and expiration dates.

CDRH Rejects My Proposed Revision of Form 3429

It didn't take long for CDRH to reject my petition. It was no surprise that the May 16, 2014, letter was signed by Nancy Stade[2]. This letter is another fine example of bureaucrat-speak, as illustrated by the following excerpts.

> Dear Dr. Hamilton:
>
> This letter responds to the above referenced petition filed on March 5, 2014, requesting that the Food and Drug Administration (FDA) revise Form FDA 3429 to indicate the appropriate classification of a medical device by reinstating a corrected third column.
>
> You assert that due to the removal of the third column in a previous revision, respondents completing the questionnaire are left without useful guidance, including the appropriate classification for the device in question. For the reasons stated below, your request is denied.
>
> …
>
> II. Discussion
>
> After careful consideration, FDA previously determined that unnecessary information had been included in Form FDA 3429 that could confuse readers. The extraneous information in the last column and in row four described merely one approach of understanding device classification, albeit not the only approach. The information in
>
> XXX
>
> the third column was therefore removed in 2012 to improve clarity.

[End of quote]

The letter contains nothing to rebut my assertion that removal of the third column leaves respondents without useful guidance. I stand by my repeated statement that the revised CQ was rendered useless for its intended purpose. Obviously, I disagree with the reasoning of the letter, just as I had disagreed with it when it appeared in the memorandum to OMB explaining and justifying the revision in the first place. The information in column 3 is anything but extraneous. How can they say its removal improves clarity? How can we communicate when we seem to have such disparate views of the rules of language and logic?

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE-FOOD AND DRUG ADMINISTRATION **GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE**			FORM APPROVED: OMB NO. 0910-0138 EXPIRATION DATE: Month Day, Year (See PRA Statement on Page 2)
PANEL MEMBER/PETITIONER			DATE
GENERIC TYPE OF DEVICE	PRODUCT CODE	CLASSIFICATION RECOMMENDATION	
1. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS?		□ YES □ NO	If "Yes," Classify in Class I and Go to item 12. If "No," go to item 2.
2. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS?		□ YES □ NO	If "Yes," Classify in Class II and go to Item 7. If "No," go to item 3.
3. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING?		□ YES □ NO	Go to item 4.
4. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE ON PREVENTING IMPAIRMENT OF HUMAN HEALTH?		□ YES □ NO	Go to item 5.
5. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY?		□ YES □ NO	Go to item 6.
6. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS (Items 3, 4, and 5)?		□ YES □ NO	If "Yes," Classify in Class III and go to Item 10. If "No," Classify in Class I and go to item 12.
7. SINCE THERE IS SUFFICIENT INFORMATION TO ESTABLISH SPECIAL CONTROLS TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS IDENTIFY BELOW THE SPECIAL CONTROLS NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE FOR CLASS II. □ Guidance Document □ Performance Standard(s) □ Device Tracking □ Testing Guidelines □ Other (Specify) _____ [LINES AS NEEDED]			Go to item 8.
8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR CLASS III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD. □ Low Priority _____ □ Medium Priority _____ □ High Priority _____ □ Not Applicable _____			Go to item 9.
9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT?		□ YES □ NO □ NOT Applicable	Go to item 11.
10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION/RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS. □ Low Priority _____ □ Medium Priority _____ □ High Priority _____ □ Not Applicable _____			Go to item 11.
11. IDENTIFY THE NEEDED RESTRICTION(S) □ Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device □ Use only by persons with specific training or experience in its use □ Use only in certain facilities □ Other (Specify) _____ _____[lines as needed]_____			
12. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO Food and Drug Administration Center for Devices and Radiological Health Office of the Center Director Regulations Staff, WO66-4436 10903 New Hampshire Avenue Silver Spring, MD 20993-0002			
FORM FDA 3429 (mm/yy)		Rev. No.	Page x

Figure 12.2 Proposed Revision for Form 3429 (FDA-2014-P-0283).

CDRH Proposes Changes to Classification/Reclassification Regulations

Not long after I submitted the Citizen Petition, a CDRH Update email announced that a webcast was scheduled for March 28, 2014 to inform the public of proposed changes in the regulations for classification and reclassification. To fully utilize the webinar in real time, it would be necessary to connect by telephone to hear the audio and to participate in the Q & A. An

internet connection was needed to view the slides. At the time, I listened to the proceedings on the phone but was unable to log on to the webinar.

Anna Staton[3], made the following statement:

> Hello, and welcome to today's FDA webinar on the medical device classification procedures proposed rule. I'm Anna Staton of CRDH's Office of Communication &Education.
> This proposed rule makes changes to CDRH's reclassification process to conform to the new streamlined procedures required by the Food & Drug Administration's Safety & Innovation Act, or FDASIA.
>
> Although it does not change the criteria, it does propose to clarify the criteria for Class III or high-risk devices. Today we have with us Nancy Stade, CDRH's Deputy Director for Policy. Following Nancy's presentation, we will open the lines for questions. Please note this session will be recorded and posted to the CDRH Learn section of fda.gov.
> [End of quote]

Nancy Stade's presentation lasted about 20 minutes; the accompanying slide show consisted of 14 slides, which I was not able to view during the program.

She mentioned that the proposed changes included the elimination of some forms; she was obviously referring to a slide in the webinar, but didn't identify the forms verbally.

Because I wasn't logged into the webinar, I guessed which forms were on the chopping block.

The following is an excerpt from the transcript of the webinar, during the Q&A following Ms. Stade's presentation.

> Coordinator: The next question comes from Mr. Leroy Hamilton. Mr. Hamilton, you may begin.
>
> Leroy Hamilton: Yes, thank you very much for the opportunity to ask a question. I want to thank Ms. Stade for her presentation and the attempts by the agency to clarify the requirements for classifying into various classes.
>
> This has been a subject of some interest to me, and she mentioned that there had been one or possibly more citizen petitions regarding classification. As the author of one of those, I have had an interest in this subject for quite some time.
>
> She mentioned in passing that there may be forms eliminated. Which forms does the agency have in mind to eliminate? Would those be Forms 3427 and 3429 or some other forms? Could you answer that please?
>
> Nancy Stade: Yes. So on Slide 11, we refer to Form 3429, Classification Questionnaire, and Form 3427, the Supplemental Data Sheet. And both of those under the proposed rule would be eliminated. As you know, they were recently revised. The proposed rule proposes to eliminate them. We feel we can get the information without the need to rely on those forms.

Leroy Hamilton: Well I'm sorry to hear that. The Classification Questionnaire has been around for a good long time and it seemed to me a useful tool when properly implemented because it provided an objective basis for anyone interested in the classification of a device to answer the questions. And until it was revised in July of 2012, it did so. It did guide one to the appropriate classification.

So it's interesting that the agency is leaning now toward eliminating these forms which were in use and they are defined in - the Classification Questionnaire is defined in the regulation.

But thank you for the answer.

[End of quote]

I was quite disappointed that CDRH had decided to eliminate Form 3429 Classification Questionnaire although I was less concerned with the Supplemental Data Sheet (Form 3427).

Later, when I accessed the slides, I found that slide 10 stated

"… interactions with stakeholders have shown the need for greater clarity In the rule, particularly concerning criteria for classification and reclassification into class III.

- **Citizen Petition FDA 2012 P 0747 challenging our use of certain forms describing criteria for classification into class III**
- **Reclassification petitions asking for certain class II devices to be classified into class III or for certain III devices to be reclassified into class II."**

[End of quote]

Here is what Ms. Stade said during the webinar while slide 10 was on the screen:

Since that time, our interactions with stakeholders have shown the need for greater clarity in the rule, particularly concerning criteria for classification and reclassification into Class III. And these interactions have include [sic] a citizen petition, they've included reclassification petitions, but they've included legal and policy challenges to how we administer our classification authority.

In particular, I'll note a citizen petition that contested our use of certain forms that seem to eliminate the - that seem to eliminate the risk-based criteria from the Class III definition. We granted that petition and actually we updated those forms. But as you'll see, we're taking things one step further with the proposed rule, and we propose to eliminate those forms.
[End of quote]

So it was my July 2012 Citizen Petition along with petitions to reclassify devices submitted by me and others which were partly responsible for the decision to revise the regulation and to eliminate the two forms.

CDRH never acknowledged that the CQ had a logical flaw. In July 2012 they deleted essential information from the CQ which rendered it useless. Now, nearly two years later, they plan to

abandon the CQ entirely. I fail to see the logic in all of this, and wondered where and when it will end. I also wondered who had made the decision.

As usual, there was no clue as to who was pulling the strings and the real reason for doing so.

I decided to try once more to seek help from the Ombudsman. As you'll see later in Chapter 13.

End Notes for Chapter 12

[1] Geeta Pamidimukkala, a Policy Analyst in the Office of Device Evaluation. (2014) GS-13, $101,914.
[2] Nancy Stade, CDRH Deputy Director for Policy (2014) ES 00, $157,234
[3] Anna Staton, General Health Scientist (2014) GS-13, $104,911