Chapter 16

Still Waiting

Forever? Or Never?

Fate of Forms 3427 and 3429

Devices Downclassified from Class III to Class II

Devices Still in Class III that Should be Downclassified

November 24, 2018. This is the concluding chapter of Part 1 – Save the CQ. Sadly, the story is incomplete, and frankly, I'm tired of waiting. FDA officials won't discuss whether they will eventually take my advice by fixing the Classification Questionnaire and continue to use it, or follow through on their plan announced two years ago to abandon Forms 3427 and 3429.

It is difficult to get a bureaucracy to change course. It bothers me that it is so difficult to get resolution to a relatively small problems like those presented so far.

As far as the classification of CES devices for depression is concerned, it may be months before the final decision is announced.

RELATIONSHIP BETWEEN FDA AND INDUSTRY

Most companies in the medical device industry avoid confrontation with the FDA. They know that the agency holds the high cards. It is easier for industry to comply with what the FDA wants

THE REVOLVING DOOR

Part 1 has dealt with what is actually a relatively minor issue: the evident misclassification of a handful of medical devices into Class III. The impact on industry and the public as a whole caused by classifying these devices in to Class III has been slight. However, the impact of the companies who make those products has been significant, and would have been even more significant if the FDA had not "seen the light" and changed them to Class II.

The final chapter is yet to be written.