A QUESTION FDA REFUSES TO ANSWER

Here's the question:

If a medical device is not life-sustaining or life-supporting, and if it is not for a use which is of substantial importance in preventing impairment of human health, and if it doesn't present a potential unreasonable risk of illness or injury, can it be in Class III?

Since February 2012, I have asked this question of a series of CDRH employees, gradually working my up the ladder to the Director of CDRH, Dr. Jeffrey Shuren. NO ONE HAS BEEN WILLING TO ANSWER THE QUESTION!

I think I know why they are unwilling to answer: they know the answer should be "No" because such a device does not satisfy the second part of the definition of Class III in the law. They don't want to answer the question because they fear that some devices were put into Class III in violation of the law they are supposed to enforce.

A SECOND UNANSWERED QUESTION:

Does the definition of Class III in the law apply to both pre-Amendments and post-Amendments devices?

On February 28, 2013, I emailed a list of 17 devices to Nancy Stade, along with an explanation of why I think some of them may have been inadvertently misclassified into Class III.

EMAIL TO NANCY STADE, FEBRUARY 28, 2013

From: Les Hamilton
Sent: Thursday, February 28, 2013 11:37 PM
To: Stade Nancy
Cc: Shuren Jeffrey
Subject: Class III devices which may be misclassified

Ms. Stade,

Thank you for your participation in the phone call with Dr. Shuren this morning.

In response to Dr. Shuren's request, I am sending you a list of seventeen devices which I think may have been misclassified into Class III. The two devices about which I am most confident are Product Codes JXK and ILX.

This is really a tentative list since I cannot claim expertise for most of these devices. I selected them because I think it is likely they do not satisfy any of the criteria in the second part of the definition of Class III in the statute.

In others words, I selected them on the basis that, in my opinion, all three of the following statements are true:

1. The device is NOT life-supporting or life-sustaining.
2. The device is NOT for a use which is of substantial importance in preventing impairment of human health.
3. The device does NOT present a potential unreasonable risk of illness or injury.

They are identified by the Product Code and device name.

Prod Code	Device Name
BWL	Apparatus, Electronanesthesia
LMY	Monitor, Skin Resistance/Skin Temperature, For Insulin Reactions
MTV	Device, Needle Destruction
JXK	Stimulator, Cranial Electrotherapy
EGJ	Device, Iontophoresis, Other Uses
HPH	Diathermy, Microwave, For Use Other Than Applying Therapeutic Deep Heat
ILX	Diathermy, Shortwave, For Use Other Than Applying Therapeutic Deep Heat
IPO	Orthosis, Pneumatic Structure, Rigid
LXF	Diathermy, Ultrasonic, For Use Other Than Applying Therapeutic Deep Heat
LOE	Stimulator, Invasive Bone Growth
LOF	Stimulator, Bone Growth, Non-Invasive
MBQ	Peripheral Electromagnetic Field (Pemf) To Aid Wound Healing
LEK	Transilluminator (Diaphanoscope)
MJS	Contrast Media, Ultrasound
MYN	Analyzer,Medical Image
NCL	Imager, Breast, Electrical Impedance
LTD	Paraquat Assay

I realize there may be differences of opinion. Certain general rules seem to be applicable. For example, I think it would be a tough argument to say that a laboratory instrument (e.g., EGJ or LTD) is life-supporting, etc.. And what about MTV, the needle destruction device?

All three Diathermy devices for use other than applying therapeutic deep heat are associated with higher power devices. The high power devices are in Class II, which suggests there is not a safety issue.

NON AVAILABILITY OF EARLIER RECORDS

It would be interesting to see exactly how the Classification Panels completed the Classification Questionnaires initially. The FDA was unable to provide completed Classification Questionnaires I requested under FOI. Were these not preserved?

In addition, my FOI request for all the versions of the Classification Questionnaire have met with little success. So far, I have not been able to obtain any questionnaire between 1977 and 1997. Weren't copies retained?

If any of these devices are considered in the future by a CDRH Panel, perhaps the Panel could be polled about the first three questions on Form 3429.

[The memo went on to discuss the LEK device which was the subject of an advisory committee meeting.]

Again, I would argue that the LEK device does not qualify for Class III because it does not satisfy any of the three conditions listed above.

I hope this information is helpful to you.

Les Hamilton