510(k) – Who Needs One and What You Actually Own When You Have One.

Moderator

Nancy Singer, Compliance-Alliance, LLC

Panelists

Daniela Drago, Ph.D. George Washington University

Barbara Fant, Pharm. D. Clinical Research Consultants, Inc.

Phil Phillips, Phillips Consulting, LLC

Susan Rolih, Meridian Bioscience, Inc.

Background

XAVIER HEALTH

- Created eight yes/no questions about interacting with FDA on issues relating to 510(k)s.
- Want to find out how the attendees at the MedCon 2017 conference view the issues.
- We will read a question and then your group (which consists of your table) should provide the answer.
- You then can compare your answer with the expert panel's answer.
- The expert panel's answer is not the "right" answer, it is just "our answer."

Expert Panel Members

XAVIER HEALTH

- Daniela Drago, Ph.D. George Washington University
- Barbara Fant, Pharm.D. Clinical Research Consultants, Inc.
- Phil Phillips, Phillips Consulting, LLC.
- Susan Rolih, Meridian Bioscience, Inc.

Process

XAVIER HEALTH

- Group should select a chair.
- Listen as the question is read.
- Group decides if the answer is yes or no.
- If the group can’t agree, the chair chooses.
- We will ask groups to vote for their choice.
- Ask for volunteers to support their selection.
- (Note: The slides with our answers will be posted after the session.)

Background

XAVIER HEALTH

- DSD submitted a 510(k) for a urological catheter.
  - DSD didn't intend to manufacture or distribute the device.
  - DSD's plan was to
    - Design it,
    - Gain FDA's permission to market it in the US, and
    - Let a contract manufacturer make the device and distribute it.
- Before the 510(k) was cleared, DSD negotiated a contract with PACE Manufacturing Company.
- DSD was to maintain ownership of the 510(k), while PACE was to be responsible for all aspects of the device's manufacturing and distribution.
- Prior to receiving the 510(k) clearance, DSD told PACE that it could manufacture and export the device.

Question 1

Is it legal for PACE to manufacture and export the device before DSD receives the 510(k) clearance?

Answer: Yes

Reference:

Exporting Unapproved Devices From the US

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ExportingMedicalDevices/ucm346617.htm

- US manufacturers that export medical devices outside the US need to register their facility and list their devices even if the devices are not distributed in the US (21 CFR 807).

- Devices that are not FDA approved or cleared for marketing in the US may be exported under 801(e)(1) of the Act provided that they are intended for export only.

- Although such devices do not meet the requirements of the FD&C Act to be sold in the US., they may be exported legally and without FDA's permission if they are class I or class II devices and they are:

    - In accordance with the specifications of the foreign purchaser;
    - Not in conflict with the laws of the country to which they are intended for export;
    - Labeled on the outside of the shipping package that they are intended for export; and
    - Not sold or offered for sale in the US

- A foreign government may require documentation from the FDA confirming that a device meets these criteria and is being exported from the US.
  - In these cases, firms may request an export Certificate of Exportability (COE) 801.
  - How to Request Export Certificates/Permits and Submitting Simple Notification provides more detailed instructions on submitting simple notification and requesting COEs under section 801(e)(1).
  - Exporters applying for a COE are required to sign a statement indicating that they meet the criteria of 21 CFR 801(e)(1).
- Some countries are requesting that companies importing medical devices have FDA approval or clearance to distribute them in the U.S.

Question 2

XAVIER HEALTH

Once DSD's 510(k) is cleared, are there conditions which PACE must meet to legally distribute the urological catheter in the United States?

If the answer is yes, list some of the conditions.

Answer: Yes

References:

- 21 CFR § 820
- 21 CFR § 801
- The FDA order classifying the device, finding it to be “substantially equivalent” and authorizing its commercial distribution in the US, including the references to general controls and any applicable special controls.

- As the manufacturer of the device, PACE needs to fulfill all relevant quality system requirements (21 CFR § 820).

- As the manufacturer and distributor of the device, PACE must ensure compliance with all general and applicable special controls.

- As the distributor of the device, PACE must be aware of the intended use for the device that was specified in the 510(k) and ensure that the intended use is not changed during distribution (21 CFR § 801.4).

Background

XAVIER HEALTH

- DSD also wanted to manufacture and distribute a cardiopulmonary bypass machine; however, DSD was worried that obtaining a 510(k) for such device might require a significant amount of time.
- DSD learned that Flick Manufacturers, Inc. was going out of business. Flick had a cleared 510(k) for this device, which it obtained in 1985.
- Flick was willing to sell the 510(k) to DSD, and the sale would take place immediately.

Question 3

XAVIER HEALTH

Can DSD buy the 510(k) from Flick without any FDA involvement?

Answer: Yes

XAVIER HEALTH

References:

- 21 CFR 807.81(a)

- Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers DRAFT (December 2014), http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM427385.pdf

- Pages 14 and 86-87, *510(k) Working Group Preliminary Report and Recommendations* (August 2010), http://www.fda.gov/downloads/aboutfda/centersoffices/cdrh/cdrhreports/ucm220784.pdf

- A 510(k) may be bought, sold, or transferred with no FDA involvement.
- The buyer should maintain documentation of the transfer of ownership in its 510(k) files, as neither registration nor listing constitutes evidence of 510(k) ownership.
- The regulations do not expressly require that Flick notifies FDA when a transfer of ownership occurs; however, DSD should list the device according to 21 CFR § 807, and Flick should update its device listing.
- FDA recommends that information relating to the ownership sale or transfer accompany all shipments to the US.
- As part of its due diligence, DSD should have evaluated any changes to the device that have taken place since the clearance in 1985.

Question 4

XAVIER HEALTH

Can DSD simply start manufacturing the device covered by Flick's 510(k) in DSD's own manufacturing facility without complying with the current design control requirements?

Answer: No

XAVIER HEALTH

Reference:

21 CFR § 820.30

- As the device that was designed, cleared by the agency and manufactured prior to enactment of SMDA in 1990 and FDA's promulgation of the QSR in 1986, Flick may not have assessed device design in accordance with today's requirements.
- Depending on the number and nature of any design changes that Flick implemented after clearance, the design history file may be sparse. Nevertheless, as a class II medical device, the cardiopulmonary bypass machine is subject to the design control requirements before and after the date of sale.
- It is suggested that as part of DSD's due diligence, Flick's design history file should be carefully examined.
- As a new manufacturer, DSD is required to have a design control system in place for the cardiopulmonary bypass machine and all future changes impacting design must conform to current requirements.

Question 5

XAVIER HEALTH

Can DSD manufacture and sell an “accessory” designed specifically for use with DSD’s recently acquired cardiopulmonary device without having FDA clearance through a 510(k)?

Answer: No

XAVIER HEALTH

References:

- Section 201(h) of the FD&C Act
- Medical Device Accessories – Describing Accessories and Classification Pathway for New Accessory Types, 12.30.2016. file:///C:/Users/Phil/Desktop/FDA%20Documents/Guidance%20Documents/Final/Program%20Guidance/510(k)%20Guidacne/Accessory%20Guidance_12.2016.pdf

- FDA will hold the final manufacturer responsible for making the decision on whether a 510(k) is required and will assess the documentation that supports distributing the accessory without 510(k) clearance.
- Accessories sold separately to hospitals or patients are devices and may need pre-market clearance.

Question 6

XAVIER HEALTH

Can DSD manufacture and sell a component of its recently acquired cardiopulmonary device without having FDA clearance through a 510(k)?

Answer: Yes

References:

- Section 201(h) of the FD&C Act
- 21 CFR 820.3(c)

- The order finding the device to be substantially equivalent and authorizing its commercial distribution in the US includes the device's components.
- DSD should ensure that the component meets the specifications described in the cleared 510(k) or are the same as the component manufactured as the result of the clearance.
- Any difference in specifications should be assessed against 21 CFR 807.81(a)(3) and K97-1 to determine whether the change requires the submission of a new 510(k).

Question 7

DSD learned that one of its distributors is marketing one of DSD's devices under its own name. The distributor has not made any changes to the device or labeling, except for putting its own name on the label.

Is it legal for the distributor to do this without submitting its own 510(k)?

Answer: Yes

XAVIER HEALTH

Reference:
21 CFR 807.85(b)(2)

- Distributors and relabelers who do not make any changes to the device or its labeling - except for putting put their own name on the label of a 510(k)-cleared device - are exempt from submitting 510(k)s.
- Any changes to the labeling, other than simply changing the trade name for the device and adding distributor identification information, may require the submission of a new 510(k).

Question 8

XAVIER HEALTH

DSD wants to market an off-the-shelf laptop computer with some of their diagnostic devices. The computer will not have any special software; it will simply provide a small convenient tool for doing minor calculations that are performed in conjunction with the use of the device. DSD is aware of the exemption from 510(k) for general purpose articles.

Can DSD ship the computer with its device without submitting a new 510(k)?

Answer: Yes

References:

- Section 201(h) of the FD&C Act
- 21 CFR 807.65(c) – General Purpose Articles

- A laptop computer with OTS software does not meet the definition of a medical device.
- Some device manufacturers consider products of this nature to be “general purpose articles … whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.” While this may be convenient, general purpose articles are devices subject to FDA regulation.