PHILLIPS CONSULTING GROUP, LLC

Deciding When to Submit a 510(k) for a Change to an Exempt Device

FDA/Xavier University
MedCon Medical Device Conference 2012
Session: 510(k) Modifications : To submit or not to submit?
May 3, 2017

Know the 510(k) Exemptions

- General exemptions
  - 21 CFR § 807.20(c) – Registration and listing
  - 21 CFR § 807.65 - Registration
  - 21 CFR § 807.85 – Premarket notification
- Device Specific exemptions
  - 21 CFR § 862-892
  - Limitations of exemptions from section 510(k) found in 21 CFR § XXX.9

Exemptions from 510(k)

- General exemptions
  - 807.20(c) – Exemptions from registration and listing

(c) Registration and listing requirements shall not pertain to any person who:

(1) Manufacturers devices for another party who both initiated the specifications and commercially distributes the device;

(2) Sterilizes devices on a contract basis for other registered facilities who commercially distribute the devices.

(3) Acts as a wholesale distributor, as defined in 807.3(s), and who does not manufacture, repackage, process, or relabel a device.

General Exemptions (continued)

- 807.65 – Exemptions from registration

(a) … raw materials or components to be used in the manufacture or assembly of a device …

(b) … devices to be used solely for veterinary purposes.

(c) … general purpose articles …

(d) … practitioners … who manufacture or otherwise alter devices solely for use in their practice.

(e) … retail establishments making final delivery or sale to the ultimate user. [including private label distribution]

(f) … devices solely for use in research, teaching, or analysis …

(h) Carriers by reason of their receipt, carriage, holding or delivery of devices …

(i) Persons who dispense devices … or … render a service necessary to provide the consumer … with a device or the benefits to be derived from the use of a device …

General Exemptions (continued)

- 807.85 – Exemptions from premarket notification

(a) A device is exempt … if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising … for commercial distribution, and the device meets one of the following conditions:

(1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

(2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

(b) A distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other labeling or otherwise affect the device shall be exempted from the premarket notification requirements of this subpart if:

(1) The device was in commercial distribution before May 28, 1976; or

(2) A premarket notification submission was filed by another person.

Changes to Devices Subject to the General Exemptions

With the exception of 21 CFR § 807.85(b), changes to devices subject to the general exemptions do not affect their regulatory status.

- The general exemptions are predicated on "activities" or "circumstances", and not device design.
- If "activities" or "circumstances" change, caution is recommended to ensure that they still fall within the exemption.

For devices subject to 21 CFR § 807.85(b):

- No device changes are permitted without filing a 510(k).
- Other than changing the device trade name and introducing information regarding the identify and location of the private label distributor, no labeling changes are permitted without filing a 510(k).

Device Specific Exemptions

- 21 CFR 862-892
  - Most class I devices
  - Select class II devices
- Exemptions are subject to limitations of “21 CFR XXX.9” and any limitations in the classification regulation.
- Examples of classification regulation limitations:
  - Sec. 880.5090 Liquid bandage – class I exempt, only as a skin protectant
  - Sec. 874.1050 Audiometer – class II, exempt if it complies with A.N.S.I. S3.6-1996, "Specification for Audiometers"

Limitations of "Device Specific" Exemptions

(a) The device is intended for a use different from the intended use of **a legally marketed device in that generic type of device**; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than **a legally marketed device in that generic type of device;** e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

Limitations (continued)

c) The device is an in vitro device that is intended:

(1)For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

A Practical Guide to Decision-Making

Is the new or modified device a class I or II IVD with an intended use identified in 21 CFR § 8XX.9(c)(1)-(9)?

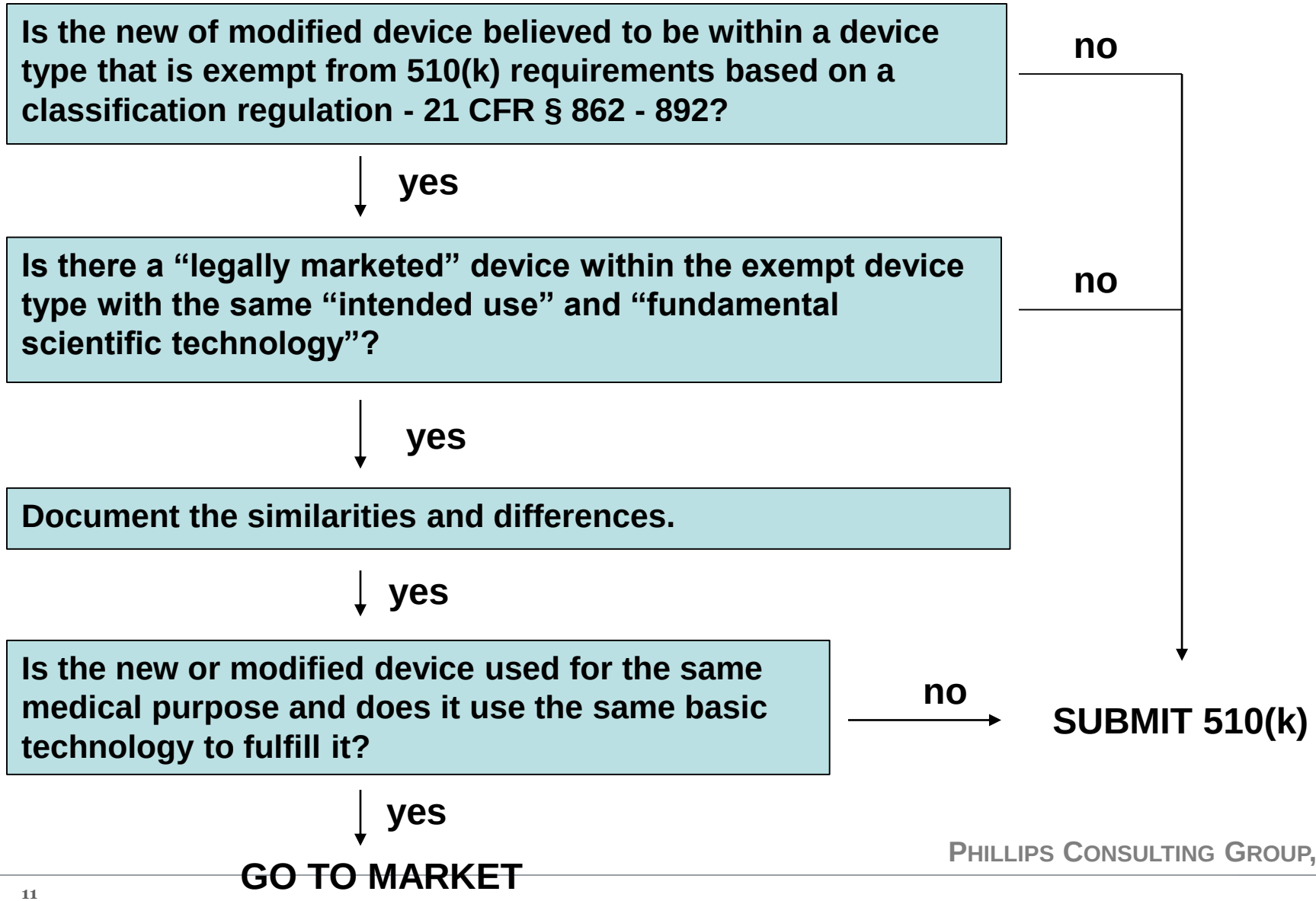
no → **GO TO NEXT SLIDE**

yes ↓

SUBMIT A 510(k)*

***If you believe that new or modified devices of the same type with an intended use identified in 21 CFR § 8XX.9(c)(1)-(9) are marketed without clearance, contact OIR.**

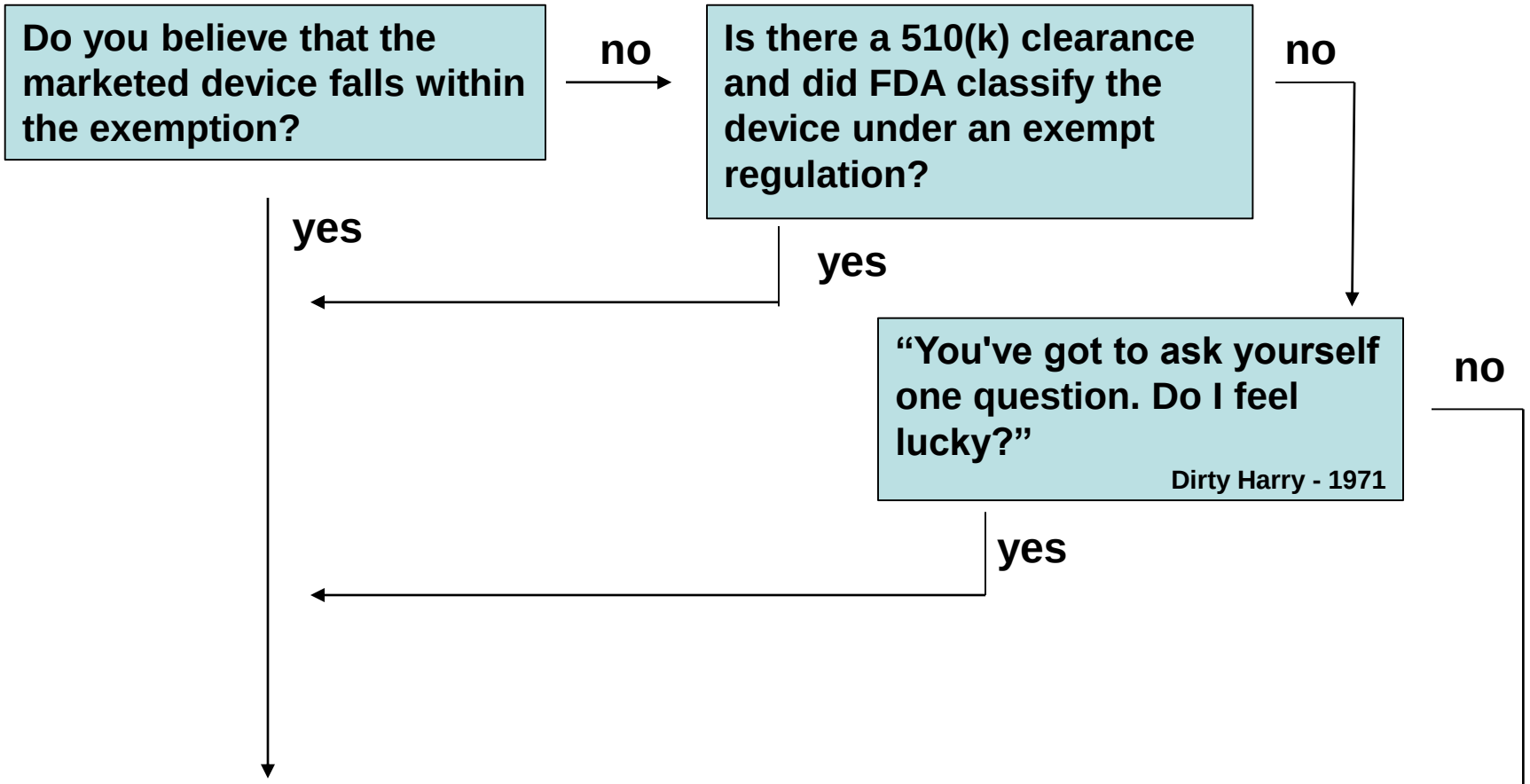
A Practical Guide to Decision-Making (continued)



What constitutes "legally marketed"?

- Commercial availability ≠ legally marketed
  - Could a competitor inappropriately conclude that a new or modified device falls within an exemption? The answer is "yes" … making the device illegally marketed!
- Evidence of being "legally marketed"
  - Perform your own *ad hoc* assessment.
    - Do you believe the marketed device falls within the exemption?
    - Is the intended use and fundamental scientific common in the exempt device type?
  - FDA's 510(k) database shows clearance and exempt classification.
  - FDA's registration and listing database suggests an exempt status.

“Legally Marketed” in the Context of Exemptions



Closing Thoughts

- Changes to devices subject to the general 510(k) exemptions are not subject to ".9" limitations.
- 510(k) clearances for certain changes that exceed the ".9" limitations expand the exemption, specifically;
  - changes in intended use; and
  - changes in fundamental scientific technology
- The commercial availability of a device that may be exempt from 510(k) does not mean that it is … INVESTIGATE THE TRUE REGULATORY STATUS BEFORE MAKING AN ASSUMPTION.