The 510(k) Exemption Sphere Grows

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Erika Ammirati, RAC, MT(ASCP)
Ammirati Regulatory Consulting

Background #1

- General resource:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm?GMPPart=864#start

- FDA exempted **Class I** devices in December 1994, and January 1996.
- Many **Class II** devices were exempted as part of FDAMA in 1997, and more recently in Dec 2016 as part of the 21st Century Cures Act (Cures Act).

Background #2

- Exempted devices are covered in Title 21 CFR Parts 862 to 892, but IVDs are covered specifically in:

- Part 862- Clinical Chemistry and Toxicology
- Part 864- Hematology and Pathology
- Part 866- Immunology and Microbiology

Exempted IVDs in Parts 862, 864, and 866 (Both Class I and Class II)

- Part 862- **Clinical Chemistry and Toxicology**
  - More then 150 test systems and various types of instrumentation

- Part 864- **Hematology and Pathology**
  - Approximately 70 test systems, various instrumentation, and various stains

- Part 866- **Immunology and Microbiology**
  - More then 115 test systems and various types of instrumentation and media

Of Special Interest …

- **Calibrators (Class II), including**
  - Primary, secondary, surrogate and multi-analyte mixture (862.1150)
- **Controls (Class I), including**
  - Unassayed, assayed, pos, neg, multi-analyte (862.1660, 864.8625), blood gases, internal PCR, not assay specific
- **Controls for allergen testing** (866.5510) still need 510(k)

A Bit of the Process

- What to do if you have a 510(k) under review for a newly exempt Class II device
  - Work with your primary reviewer; will ask that the submission be withdrawn

- Impact to a Class II IVD under review that includes calibrators and controls
  - 510(k) Summary will need to be edited to remove all details related to exempt components

But Then- We Have the Reserved List

- The Reserved List covers devices within all three regulation numbers (862, 864, and 866) and are known as the ".9 limitations."

- The .9 Limitations are cited as 862.9, 864.9 and 866.9 (same verbiage).

Sec. 862.9 Limitations of Exemptions from 510(k)s (#1)

- … “in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality.”
- Need to comply with (a), (b), and (c)

Sec. 862.9 Limitations of Exemptions from 510(k)s (#2)

- (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** (emphasis added);

Sec. 862.9 Limitations of Exemptions from 510(k)s (#3)

- (b) The modified device operates using a different fundamental scientific technology than a legally marketed device, … **in vitro diagnostic device** detects or identifies infectious agents by using a DNA probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Sec. 862.9 Limitations of Exemptions from 510(k)s (#4)

- (c) The device is an in vitro device that is intended (9 items):
  - (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;

Sec. 862.9 Limitations of Exemptions from 510(k)s (#5)

- (3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as 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;

Sec. 862.9 Limitations of Exemptions from 510(k)s (#6)

- (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;

Sec. 862.9 Limitations of Exemptions from 510(k)s (#7)

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

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

“Exempt Does Not Mean Nothing”

- What needs to be done if exempt:
  - Register and list
  - Comply with QSR/GMP (21 CFR part 820)
  - Maintain Design History File

GMP Exempt

- A few very simple Class I devices are QSR exempt (see examples below) if so, just need to maintain general records (820.180) and complaint files (820.198)

List of QSR Exempt #1

- general purpose laboratory equipment labeled or promoted for a specific medical use
- thin-layer chromatography system for clinical use.
- dye and chemical solution stains
- cell and tissue culture supplies and equipment
- tissue processing equipment
- specimen transport and storage container (if not sterile)
- microscopes and accessories

List of QSR Exempt #2

- general purpose reagent.
- anaerobic chamber.
- manual colony counter
- automated medium dispensing and stacking device
- microbiological incubator

Questions