

## 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

**PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES**

1. The authority citation for 21 CFR part 862 continues to read as follows:

**Authority:** Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 862.2230 is amended by revising paragraph (b) to read as follows:

**§ 862.2230 Chromatographic separation material for clinical use.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

**PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES**

3. The authority citation for 21 CFR part 866 continues to read as follows:

**Authority:** Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

4. Section 866.2160 is amended by revising paragraph (b) to read as follows:

**§ 866.2160 Coagulase plasma.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

5. Section 866.3720 is amended by revising paragraph (b) to read as follows:

**§ 866.3720 Streptococcus spp. exoenzyme reagents.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

6. Section 866.5520 is amended by revising paragraph (b) to read as follows:

**§ 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

7. Section 866.5530 is amended by revising paragraph (b) to read as follows:

**§ 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

8. Section 866.5860 is amended by revising paragraph (b) to read as follows:

**§ 866.5860 Total spinal fluid immunological test system.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

**PART 868—ANESTHESIOLOGY DEVICES**

9. The authority citation for 21 CFR part 868 continues to read as follows:

**Authority:** Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

10. Section 868.1100 is amended by revising paragraph (b) to read as follows:

**§ 868.1100 Arterial blood sampling kit.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

11. Section 868.1575 is amended by revising paragraph (b) to read as follows:

**§ 868.1575 Gas collection vessel.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

12. Section 868.1870 is amended by revising paragraph (b) to read as follows:

**§ 868.1870 Gas volume calibrator.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

13. Section 868.1975 is amended by revising paragraph (b) to read as follows:

**§ 868.1975 Water vapor analyzer.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

14. Section 868.2300 is amended by revising paragraph (b) to read as follows:

**§ 868.2300 Bourdon gauge flowmeter.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

15. Section 868.2320 is amended by revising paragraph (b) to read as follows:

**§ 868.2320 Uncompensated thorpe tube flowmeter.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

16. Section 868.2340 is amended by revising paragraph (b) to read as follows:

**§ 868.2340 Compensated thorpe tube flowmeter.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

17. Section 868.2350 is amended by revising paragraph (b) to read as follows:

**§ 868.2350 Gas calibration flowmeter.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

18. Section 868.2610 is amended by revising paragraph (b) to read as follows:

**§ 868.2610 Gas pressure gauge.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

19. Section 868.2620 is amended by revising paragraph (b) to read as follows:

**§ 868.2620 Gas pressure calibrator.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

20. Section 868.2700 is amended by revising paragraph (b) to read as follows:

**§ 868.2700 Pressure regulator.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

21. Section 868.2875 is amended by revising paragraph (b) to read as follows:

**§ 868.2875 Differential pressure transducer.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

22. Section 868.2885 is amended by revising paragraph (b) to read as follows:

**§ 868.2885 Gas flow transducer.**

\* \* \* \* \*

(b) *Classification.* Class I. The device is exempt from the premarket