Food and Drug Administration, HHS

§ 890.5730 Cold pack.
(a) Identification. A cold pack is a device intended for medical purposes that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel capable of forming to the contour of the body and that provides cold therapy for body surfaces.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 890.5710 Hot or cold disposable pack.
(a) Identification. A hot or cold disposable pack is a device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.
(b) Classification. Class I (general controls). Except when intended for use on infants, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §890.9.

§ 890.5720 Water circulating hot or cold pack.
(a) Identification. A water circulating hot or cold pack is a device intended for medical purposes that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.
(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §890.9.

§ 890.5730 Moist heat pack.
(a) Identification. A moist heat pack is a device intended for medical purposes that consists of silica gel in a