both the support and the patient, dev-
ices where the patient is lifted by a
sling from a bed to be weighed, and dev-
ices where the patient is placed on the
scale platform to be weighed. The de-
vice may be mechanical, battery pow-
ered, or AC-powered and may include
transducers, electronic signal amplifi-
cation, conditioning and display equip-
ment.

(b) Classification. Class I (general con-
trols). The device is exempt from the
premarket notification procedures in
subpart E of part 807 of this chapter
subject to the limitations in §880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 61
FR 1123, Jan. 16, 1996; 66 FR 38803, July 25,
2001]

§ 880.2740 Surgical sponge scale.

(a) Identification. A surgical sponge
scale is a nonelectrically powered de-
vice used to weigh surgical sponges
that have been used to absorb blood
during surgery so that, by comparison
with the known dry weight of the
sponges, an estimate may be made of
the blood lost by the patient during
surgery.

(b) Classification. Class I (general con-
trols). The device is exempt from the
premarket notification procedures in
subpart E of part 807 of this chapter,
subject to the limitations in §880.9. The
device also is exempt from the current
good manufacturing practice require-
ments of the quality system regulation
in part 820 of this chapter, with the ex-
ception of §820.180, with respect to gen-
eral requirements concerning records,
and §820.198, with respect to complaint
files.

[45 FR 69682, Oct. 21, 1980, as amended at 66
FR 38804, July 25, 2001]

§ 880.2800 Sterilization process indi-

cator.

(a) Biological sterilization process indi-
cator—(1) Identification. A biological
sterilization process indicator is a de-
vice intended for use by a health care
provider to accompany products being
sterilized through a sterilization proce-
dure and to monitor adequacy of steri-
lization. The device consists of a
known number of microorganisms, of
known resistance to the mode of steri-
lization, in or on a carrier and enclosed
in a protective package. Subsequent
growth or failure of the microorga-

§ 880.2910 Clinical electronic ther-

(a) Identification. A clinical electronic
thermometer is a device used to meas-
ure the body temperature of a patient
by means of a transducer coupled with
an electronic signal amplification, con-
ditioning, and display unit. The trans-
ducer may be in a detachable probe
with or without a disposable cover.

(b) Classification. Class II (perform-
ance standards).

§ 880.2900 Clinical color change ther-

(a) Identification. A clinical color
change thermometer is a disposable de-
vice used to measure a patient’s oral,
rectal, or axillary (armpit) body tem-
perature. The device records body tem-
perature by use of heat sensitive
chemicals which are sealed at the end
of a plastic or metal strip. Body heat
causes a stable color change in the
heat sensitive chemicals.

(b) Classification. Class I (general con-
trols). The device is exempt from the
premarket notification procedures in
subpart E of part 807 of this chapter,
subject to the limitations in §880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 61
FR 1123, Jan. 16, 1996; 66 FR 38804, July 25,
2001]