Food and Drug Administration, HHS

§ 882.4300 Manual cranial drills, burrs, trephines, and their accessories
(a) Identification. Manual cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that are used without a power source on a patient’s skull.
(b) Classification. Class II (performance standards).

§ 882.4305 Powered compound cranial drills, burrs, trephines, and their accessories
(a) Identification. Powered compound cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient’s skull. The instruments employ a clutch mechanism to disengage the tip of the instrument after penetrating the skull to prevent plunging of the tip into the brain.
(b) Classification. Class II (performance standards).

§ 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories
(a) Identification. Powered simple cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient’s skull. The instruments are used with a power source but do not have a clutch mechanism to disengage the tip after penetrating the skull.
(b) Classification. Class II (performance standards).

§ 882.4325 Cranial drill handpiece (brace).
(a) Identification. A cranial drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools that are used on a patient’s skull.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §882.9.

§ 882.4360 Electric cranial drill motor.
(a) Identification. An electric cranial drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits on a patient’s skull.
(b) Classification. Class II (performance standards).

§ 882.4370 Pneumatic cranial drill motor.
(a) Identification. A pneumatic cranial drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits on a patient’s skull.
(b) Classification. Class II (performance standards).

§ 882.4400 Radiofrequency lesion generator.
(a) Identification. A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.
(b) Classification. Class II (performance standards).

§ 882.4440 Neurosurgical headrests.
(a) Identification. A neurosurgical headrest is a device used to support the patient’s head during a surgical procedure.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §882.9.

§ 882.4460 Neurosurgical head holder (skull clamp).
(a) Identification. A neurosurgical head holder (skull clamp) is a device used to clamp the patient’s skull to hold head and neck in a particular position during surgical procedures.
(b) Classification. Class II (performance standards).

§ 882.4500 Cranioplasty material forming instrument.
(a) Identification. A cranioplasty material forming instrument is a roller used in the preparation and forming of cranioplasty (skull repair) materials.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in 443