§ 882.5070 Bite block.

(a) Identification. A bite block is a device inserted into a patient’s mouth to protect the tongue and teeth while the patient is having convulsions.

(b) Classification. Class II (performance standards).

§ 882.5150 Intravascular occluding catheter.

(a) Identification. An intravascular occluding catheter is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels) of intracranial blood vessels.

(b) Classification. Class III (premarket approval).

(c) Date PMA or notice of completion of a PDP is required. A PMA or a declared completed PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any intravascular occluding catheter that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an intravascular occluding catheter that was in commercial distribution before May 28, 1976. Any other intravascular occluding catheter shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 882.5250 Burr hole cover.

(a) Identification. A burr hole cover is a plastic or metal device used to cover or plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery.

(b) Classification. Class II (performance standards).

§ 882.5275 Nerve cuff.

(a) Identification. A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).