May 16, 2022

Re: Premarket notification submission exemption for CHECKPOINT EDGE™ Nerve Cutting Kit, 9250

To Whom It May Concern,

The CHECKPOINT EDGE™ Nerve Cutting Kit is a single-use, sterile kit intended to provide surgeon aid in transecting nerve tissue for the purpose of nerve graft preparation, nerve repair, or removal of exposed nerve. The kit includes three circumferential nerve constraining forceps, two blades, and a silicone visibility background.

The following information is being provided as rationale for premarket notification submission exemption.

Per *21 CFR 882.4535 Nonpowered neurosurgical instrument*, these hand instruments which are used during neurosurgical procedures to cut, hold, or manipulate tissue are classified as Class I medical devices, which are exempt from the premarket notification procedures in subpart E of part 807 subject to the limitations in §882.9. The limitations of 21 CFR §882.9 are excluded in that:

- The Checkpoint Edge Nerve Cutting Kit has existing or reasonably foreseeable characteristics of commercially distributed devices within its generic type;
- The intended use is in line with the intended use of an already legally marketed device in that generic type of device (scalpels, surgical backgrounds, nerve and tendon holding forceps);
- There are no fundamental changes in technology when compared to its generic type;
- The kit is not, nor does it contain any *in vitro* diagnostic or assaying device.

This classification exempts the kit from premarket notification procedures in subpart E of part 807, however, the kit will be listed prior to release, and the contract manufacturing and sterilization establishments are registered. This Class I medical device is documented in accordance with the FDA's general control requirements and Checkpoint Surgical's procedural requirements under the product code HAO.

Any further questions may be directed to the contacts below.

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