for use in intervertebral fusion procedures as identified in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has, on or before October 30, 2025, been found to be substantially equivalent to any spinal sphere device for use in intervertebral fusion procedures identified in paragraph (a) of this section, that was in commercial distribution before May 28, 1976. Any other spinal sphere device for use in intervertebral fusion procedures identified in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[88 FR 18990, 18993, Mar. 30, 2023]

§ 888.3085 Intervertebral body graft containment device.

(a) *Identification.* An intervertebral body graft containment device is a non-rigid, implanted spinal device that is designed to contain bone graft within its internal cavity. The device is inserted into the intervertebral body space of the spine and is intended as an adjunct to intervertebral body fusion.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must include an assessment of any adverse events observed during clinical use, as well as intervertebral body fusion, and compare this to a clinically acceptable fusion rate.

(2) Non-clinical performance testing must demonstrate the mechanical function and durability of the implant, as well as the ability of the device to be inserted, deployed, and filled with bone graft consistently.

(3) Device must be demonstrated to be biocompatible.

(4) Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components, and device-specific instruments.

(5) Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.

(6) Labeling must bear all information required for the safe and effective use of the device, specifically including the following:

(i) A clear description of the technological features of the device including identification of device materials, compatible components in the fusion construct, and the principles of device operation;

(ii) Intended use and indications for use, including levels of fixation;

(iii) Identification of magnetic resonance (MR) compatibility status;

(iv) Cleaning and sterilization instructions for devices and instruments that are provided nonsterile to the end user; and

(v) Detailed instructions of each surgical step, including device removal.

[89 FR 71158, Sept. 3, 2024]

§ 888.3090 Intraoperative orthopedic strain sensor.

(a) *Identification.* A strain sensor device is an adjunct tool intended to measure strain on an orthopedic implant in the intraoperative setting only. The device is not intended to provide diagnostic information or influence clinical decision making.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be conducted:

(i) Mechanical testing to evaluate the effect of the device on the mechanical performance of the implant and to characterize the mechanical limits of the components used with the implant; and

(ii) Accuracy and repeatability testing of strain measurements.

(2) Usability testing must evaluate the effect of the device on the performance of the surgical procedure.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance testing must support the sterility and shelf life of the patient-contacting components of the device.

(5) Software verification, validation, and hazard analysis must be performed.