

making the palatal mold, and assessment of issues with the device that may require service by the manufacturer.

[82 FR 35069, July 28, 2017]

§ 876.5982 Ingested, transient, space occupying device for weight management and/or weight loss.

(a) *Identification.* This device is an ingested material that transiently occupies space in the stomach. The device passes from the body via the natural gastrointestinal tract.

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

(1) The patient-contacting components of the device must be demonstrated to be biocompatible for its intended use.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, as follows:

(i) Performance bench testing in a simulated use model must evaluate device disintegration and device hydration state throughout the gastrointestinal tract;

(ii) Bioburden and moisture content assessments must evaluate device infection risk throughout the labeled shelf life; and

(iii) Performance data must support the shelf life of the device by demonstrating continued package integrity and device functionality over the labeled shelf life.

(3) Clinical performance testing must demonstrate the device performs as intended and evaluate the following:

(i) Weight change;

(ii) All adverse events, including obstruction, dilation, diarrhea, constipation, and dehydration; and

(iii) Interaction with representative medications.

(4) Physician and patient device labeling must state:

(i) The clinical benefit of the device as assessed by using percent total body weight loss;

(ii) Treatment must be offered in combination with diet and exercise;

(iii) Instructions on how to use the device as intended including how to avoid interaction with medication; and

(iv) The shelf life of the device.

[86 FR 70372, Dec. 10, 2021]

§ 876.5985 Enzyme packed cartridge.

(a) *Identification.* An enzyme packed cartridge is an *ex vivo* prescription device that is used in enzymatic hydrolysis of macronutrients into their essential nutrient forms at the time of delivery. The device consists of an outer casing containing an inert polymer with a covalently bound enzyme through which nutritional formula is directed. The device fits in line with enteral feeding systems.

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

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

(2) *In vivo* testing must be performed and must demonstrate that the device causes neither an adverse tissue response nor adverse performance.

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

(i) Mechanical testing to demonstrate that the device can withstand clinical forces;

(ii) Flow rate and leakage testing to demonstrate that the device does not impede the flow of enteral formula;

(iii) Demonstration of enzymatic effect on intended macronutrient;

(iv) The amount of enzyme that exits the cartridge must be characterized;

(v) Validation that the device does not adversely impact the nutritional composition of enteral formula; and

(vi) Validation that the device does not impede flow alarms on enteral feeding pumps.

(4) Human factors testing must be performed to characterize use error risks.

(5) Performance data must support shelf life by demonstrating package integrity and device functionality over the identified shelf life.

(6) Labeling must include the following:

(i) A detailed summary of *in vivo* testing pertinent to use of the device, including device-related adverse events;

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(ii) A detailed summary of compatible formulas that is supported by non-clinical testing, including the expected enzymatic conversion as a percentage;

(iii) Detailed instructions on how to place the device into an enteral feeding circuit;

(iv) A warning regarding the possibility for misconnections; and

(v) Expiration date or shelf life.

(7) Patient labeling must be provided and must include:

(i) Relevant warnings, precautions, adverse effects, and complications;

(ii) A description of the device and how it operates;

(iii) Instructions on how to correctly use the device; and

(iv) The benefits and risks associated with the use of the device.

[82 FR 47971, Oct. 16, 2017]

§ 876.5990 Extracorporeal shock wave lithotripter.

(a) *Identification.* An extracorporeal shock wave lithotripter is a device that focuses ultrasonic shock waves into the body to noninvasively fragment urinary calculi within the kidney or ureter. The primary components of the device are a shock wave generator, high voltage generator, control console, imaging/localization system, and patient table. Prior to treatment, the urinary stone is targeted using either an integral or stand-alone localization/imaging system. Shock waves are typically generated using electrostatic spark discharge (spark gap), electromagnetically repelled membranes, or piezoelectric crystal arrays, and focused onto the stone with either a specially designed reflector, dish, or acoustic lens. The shock waves are created under water within the shock wave generator, and are transferred to the patient's body using an appropriate acoustic interface. After the stone has been fragmented by the focused shock waves, the fragments pass out of the body with the patient's urine.

(b) *Classification.* Class II (special controls) (FDA guidance document: "Guidance for the Content of Pre-market Notifications (510(k)'s) for Extracorporeal Shock Wave Lithotripters Indicated for the Frag-

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mentation of Kidney and Ureteral Calculi.”)

[65 FR 48612, Aug. 9, 2000]

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

Subpart A—General Provisions

Sec.

878.1 Scope.

878.3 Effective dates of requirement for pre-market approval.

878.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

878.1800 Speculum and accessories.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

878.3250 External facial fracture fixation appliance.

878.3300 Surgical mesh.

878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.

878.3510 Carbon dioxide gas controlled tissue expander.

878.3530 Silicone inflatable breast prosthesis.

878.3540 Silicone gel-filled breast prosthesis.

878.3550 Chin prosthesis.

878.3590 Ear prosthesis.

878.3610 Esophageal prosthesis.

878.3680 Nose prosthesis.

878.3720 Tracheal prosthesis.

878.3750 External prosthesis adhesive.

878.3800 External aesthetic restoration prosthesis.

878.3900 Inflatable extremity splint.

878.3910 Noninflatable extremity splint.

878.3925 Plastic surgery kit and accessories.

Subpart E—Surgical Devices

878.4010 Tissue adhesive.

878.4011 Tissue adhesive with adjunct wound closure device for topical approximation of skin.

878.4014 Nonresorbable gauze/sponge for external use.

878.4015 Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive.

878.4018 Hydrophilic wound dressing.

878.4020 Occlusive wound dressing.

878.4022 Hydrogel wound dressing and burn dressing.

878.4025 Silicone sheeting.

878.4040 Surgical apparel.

878.4100 Organ bag.

878.4160 Surgical camera and accessories.