



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2016-N-4661]

Gastroenterology-Urology Devices; Manual Gastroenterology-Urology Surgical Instruments and Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the identification of manual gastroenterology-urology surgical instruments and accessories to reflect that the device does not include specialized surgical instrumentation for use with urogynecologic surgical mesh specifically intended for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures (“specialized surgical instrumentation for use with urogynecologic surgical mesh”). These amendments are being made to reflect changes made in the recently issued final reclassification order for specialized surgical instrumentation for use with urogynecologic surgical mesh.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION: FDA is amending § 876.4730 (21 CFR 876.4730, Manual gastroenterology-urology surgical instrument and accessories), by adding language to the identification of the device to reflect that specialized surgical instrumentation for use with urogynecologic surgical mesh is no longer regulated under § 876.4730.

In the Federal Register of November 23, 1983 (48 FR 53012), FDA issued a final rule classifying manual gastroenterology-urology surgical instrument and accessories into class I under § 876.4730 (48 FR 53012 at 53025). Certain specialized surgical instrumentation for use with urogynecologic surgical mesh was regulated as class I devices under that regulation. In the Federal Register of January 6, 2017 (82 FR 1598), FDA issued a final order reclassifying specialized surgical instrumentation for use with urogynecologic surgical mesh from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification. As a result of that final reclassification order, FDA is amending the identification at § 876.4730(a) to reflect that specialized surgical instrumentation for use with urogynecologic surgical mesh is now regulated under 21 CFR 884.4910.

FDA finds good cause for issuing this amendment as a final rule without notice and comment because this rule only updates the identification of the device under § 876.4730 to reflect changes made in the recently issued final reclassification order for specialized surgical instrumentation for use with urogynecologic surgical mesh (5 U.S.C. 553(b)(B)). In addition, FDA finds good cause for this amendment to become effective on the date of publication of this action. The Administrative Procedure Act allows an effective date less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendment to § 876.4730 does not impose any new regulatory requirements on affected parties. As a result,

affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for this amendment to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 876

Gastroenterology-urology devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876--GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Amend § 876.4730 by revising paragraph (a) to read as follows:

§876.4730 Manual gastroenterology-urology surgical instrument and accessories.

(a) Identification. A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, nonself-retaining retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop. A manual surgical instrument that is intended specifically for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures are classified under § 884.4910 of this chapter.

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Dated: February 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-03997 Filed: 2/28/2017 8:45 am; Publication Date: 3/1/2017]