February 7, 2019

ACell, Inc.
Ms. Andrea Artman
Sr. Regulatory Affairs Manager
6640 Eli Whitney Drive Suite 200
Columbia, Maryland 21046

Re: K182259
Trade/Device Name: Gentrix Surgical Matrix, Gentrix Surgical Matrix Hiatal
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, OXH, OWV
Dated: January 25, 2019
Received: January 28, 2019

Dear Ms. Artman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182259

Device Name
Gentrix® Surgical Matrix (3-Layer, 6-Layer, and 8-Layer)
Gentrix® Surgical Matrix Hiatal (6-Layer and 8-Layer)

Indications for Use *(Describe)*
Gentrix® Surgical Matrix (3-layer) is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological, gastroenterological, or plastic & reconstructive surgery. Reinforcement of soft tissue within urological, gastroenterological, and plastic & reconstructive surgery includes, but is not limited to, the following open or laparoscopic procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. The Gentrix® Surgical Matrix (3-layer) minimizes tissue attachment to the device in case of direct contact with viscera.

Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Hiatal (6-layer and 8-Layer) are intended for implantation to reinforce soft tissue where weakness exists in patients requiring gastroenterological or plastic & reconstructive surgery. Reinforcement of soft tissue within gastroenterological and plastic & reconstructive surgery includes, but is not limited to, the following open or laparoscopic procedures: hernia (e.g.: hiatal/diaphragmatic) and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. The Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Hiatal (6-layer and 8-Layer) minimizes tissue attachment to the device in case of direct contact with viscera.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
Gentrix® Surgical Matrix
Gentrix® Surgical Matrix Hiatal

Submitter: ACell, Inc.
6640 Eli Whitney Drive
Columbia, MD 21046

Contact Person: Andrea Pilon Artman
Contact Title: Associate Director, Regulatory Affairs
Phone: 410-953-8549
Facsimile: 410-715-4511

Date Prepared: January 15, 2019

Trade Name: Gentrix® Surgical Matrix, Gentrix® Surgical Matrix Hiatal

Common Name: Animal-Derived, Extracellular Matrix Surgical Product

Classification Name: Mesh, Surgical, Collagen, Plastic and Reconstructive Surgery

Regulation Number: 21 C.F.R. § 878.3300

Regulatory Class: Class II

FDA Product Code: FTM, OXH, OWV

Predicate Device: Gentrix® Surgical Matrix 2-Layer, 3-Layer, 6- Layer, 8-Layer (K162554)
Reference Devices: The SURGISIS® Biodesign Tissue Graft (K073391, Cook Biotech Inc.)
Biodesign® Diaphragmatic Hernia Graft (K133011, Cook Biotech Inc.)

Device Description

Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Hiatal device configurations are composed of porcine-derived extracellular matrix scaffolds, specifically known as urinary bladder matrix ("UBM"). The implantable biomaterial is a resorbable extracellular matrix scaffold that provides mechanical reinforcement of soft tissue and will incorporate (remodel) into the body through cellular infiltration, capillary growth, and integration by the surrounding host tissue (as demonstrated in porcine models of ventral and hiatal hernia), while minimizing tissue attachment to the device in case of direct contact with viscera (as demonstrated in a preclinical rabbit cecal abrasion model). The devices are supplied in multiple layered sheet configurations in sizes up to 10 cm x 15 cm, and are available in rectangular and u-shape variations. All device configurations are packaged in double peel-open sterile barrier system. The devices are terminally sterilized using electron beam irradiation. The devices are intended for one time use.

Intended Use/Indications for Use

Gentrix® Surgical Matrix (3-layer) is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological, gastroenterological, or plastic & reconstructive surgery. Reinforcement of soft tissue within urological, gastroenterological, and plastic &

reconstructive surgery includes, but is not limited to, the following open or laparoscopic procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. The Gentrix® Surgical Matrix (3-layer) minimizes tissue attachment to the device in case of direct contact with viscera.

Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Hiatal (6-layer and 8-Layer) are intended for implantation to reinforce soft tissue where weakness exists in patients requiring gastroenterological or plastic & reconstructive surgery. Reinforcement of soft tissue within gastroenterological and plastic & reconstructive surgery includes, but is not limited to, the following open or laparoscopic procedures: hernia (e.g.: hiatal/diaphragmatic) and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. The Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Hiatal (6-layer and 8-Layer) minimizes tissue attachment to the device in case of direct contact with viscera.

Summary of Technological Characteristics and Applicable Performance Data: The addition the Gentrix Surgical Matrix Hiatal device configuration, including the u-shape design, is supported by pre-clinical and clinical evidence. The u-shape design was studied in a pre-clinical porcine hiatal hernia model. A total of ten (10) pigs were used in this hiatal hernia model. Animals were randomly assigned to the reinforcement group or control group. The animals were survived for 60 days. Laparoscopic surgeries were successfully completed in all 10 animals. There was no noted damage or insult to the GSMH U-Shape device for any animal. All animals recovered from the surgery and there were no adverse events seen during the in-life portion of the study. Just prior to necropsy, endoscopic evaluation revealed mild narrowing at the distal end of the esophagus in all animals (non-reinforced control and reinforced). As all animals gained weight over the study with no evidence of GI complications, this narrowing was considered a result of the surgical procedure, rather than from the device, and was not considered clinically significant by the independent clinical pathologist.

The results demonstrated acceptable tissue responses with no instances of herniation or esophageal erosion or trauma, and concluded that the pre-fabricated u-shape did not impact product performance. In addition, data from clinical publications summarized below provided support for the addition of the new Gentrix® Surgical Matrix Hiatal configuration (u-shape) to the product line. No mechanical or biocompatibility testing were completed in support of this clearance as Gentrix Surgical Matrix is acting as its own predicate device. A table comparing the key features of the subject and predicate device is provided below.

Summary of Applicable Performance Data – Indications: Bench testing and pre-clinical animal testing was conducted to support the addition of laparoscopic use, minimized tissue attachment compared to the collagen mesh control, and specific hiatal / diaphragmatic hernia to the previously cleared indications for use statement. The laparoscopic and specific hiatal / diaphragmatic hernia indications were studied in a porcine hiatal hernia repair model; results demonstrated acceptable tissue responses with no instances of herniation or esophageal erosion or trauma over the 60- day study duration.

The formation of tissue attachments was evaluated in a New Zealand white rabbit cecal abrasion model; the results, presented in the tables below, demonstrated substantially equivalent tissue attachment to the device compared to the collagen mesh control in case of direct contact with viscera.

Group	Day 14				
	% Animals with Attachments (n = 6 animals / group)	**Average Attachment Severity Score ***	**Total # Attachments**	**Average Estimated Attachment Diameter**	**Average % Device Covered with Attachments**
Control (No reinforcement)†	50% (3 of 6)	1.0 ± 1.1	5	1.4 cm	N/A
Gentrix Surgical Matrix 3-Layer	0% (0 of 6)	0.0 ± 0.0	0	0 cm	0%
Gentrix Surgical Matrix 6-Layer	0% (0 of 6)	0.0 ± 0.0	0	0 cm	0%
Gentrix Surgical Matrix 8-Layer	0% (0 of 6)	0.0 ± 0.0	0	0 cm	0%
Collagen Mesh Control	17% (1 of 6)	0.2 ± 0.4	1	1.0 cm	0.83%

Group	Day 90				
	% Animals with Attachments (n = 6 animals / group)	**Average Attachment Severity Score ***	**Total # Attachments**	**Average Estimated Attachment Diameter**	**Average % Device Covered with Attachments**
Control (No reinforcement)†	33% (2 of 6)	0.7 ± 1.0	3	2.75 cm	N/A
Gentrix Surgical Matrix 3-Layer	17% (1 of 6)	0.3 ± 0.8	1	1 cm	4.17%
Gentrix Surgical Matrix 6-Layer	33% (2 of 6)	0.7 ± 1.0	3	0.5 cm	0.83%
Gentrix Surgical Matrix 8-Layer	0% (0 of 6)	0.0 ± 0.0	0	0 cm	0%
Collagen Mesh Control	67% (4 of 6)	1.0 ± 1.1	5	1.6 cm	14.16%

* The attachment severity scoring is a method that assesses the tenacity with which tissues are adhered. The highest average reported score in this model was a score of 1, which describes an easily detachable tissue attachment where applicable tissues can be safely separated from the study site with minimal use of blunt surgical tools.

† The control (no reinforcement) group is a cohort of animals that underwent the same surgical procedure, but no device was placed at the site of the abrasion.

Histological analysis completed in the porcine and rabbit models demonstrated that the subject devices undergo remodeling through cellular infiltration, capillary growth, and integration by the surrounding host tissue. In addition, data from various published clinical and pre-clinical animal studies provided further support for the addition of the laparoscopic use, minimal tissue attachment, and specific hiatal / diaphragmatic hernia indications.

Summary of Clinical Data: There were no premarket clinical trials conducted to support the substantial equivalence of the subject devices. However, six (6) separate retrospective publications from the clinical setting were included in this submission, demonstrating the safety and performance of the subject devices for the enclosed indications.

Six (6) publications were identified for the hiatal hernia indication based on specific search criteria that was limited to English language publications and publications with data was the same as the labeled indications for the Gentrix Surgical Matrix. The search was unlimited as to the type of clinical research (e.g. randomized trials, prospective trials, treatment studies, case reports included). Four of the six submitted clinical references (2, 4-6) utilized an anatomic classification system for defining the etiology of hiatal hernias (Types I-IV), as defined by the Society of American Gastrointestinal and Endoscopic Surgeons. The remaining two publications

described the defect sizes of the hiatus. All surgeons evaluated patient symptoms when assessing the severity of a hiatal hernia and the need for surgical intervention, such as shortness of breath, nausea, dysphagia, and severe reflux. A detailed summary of the published clinical data is provided below.

1. Retrospective single-surgeon study of 62 patients who underwent Laparoscopic Hiatal Hernia Repair with diaphragmatic reinforcement using GSM 6-Layer[1]. All patients had a defect size of greater than 4 cm. The severity of the defects was not defined. A primary hiatal hernia repair with either a fundoplication or concomitant bariatric procedure (Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy, or gastrojejunostomy anastomosis revision) was performed for all patients.

Patient Demographics				
Sample Size		Mean Age	Age Range	Mean BMI
Total 62	F: 53 / M: 9	62 years	32–83 years	32.7 kg/m^2

No intraoperative complications were noted. The follow up was conducted for all patients at a minimum of 3 months at which time patients underwent a contrast upper gastrointestinal series. Postoperatively, successful endoscopic balloon dilation for dysphagia was conducted on 3 patients with no re-operative intervention. A radiographic recurrence rate of 22% (9/41) was identified during 3 month follow up; one (2.4%) became symptomatic and required operative revision 22 months after initial operative intervention.

2. A retrospective review of 121 patients who underwent isolated paraesophageal hiatal hernia (PHH) repair by 3 surgeons was performed[2]. Fifty-six (56, 46.3%) were reinforced with Urinary Bladder Matrix (UBM) and sixty-five (65, 53.7%) were not reinforced. The decision of whether to use UBM was left to the surgeon. Patients in the UBM group had large defects or crural fibers attenuated. The size or severity of each defect was not defined. Fundoplication and cruroplasty reinforced with the use of Gentrix Surgical Matrix were compared to fundoplication and suture cruroplasty alone. Cases were performed robotically or laparoscopically with no conversions to open.

   There were 17 postoperative complications that occurred within 30 days of the procedure: 11 in the UBM group and 6 in the non-UBM group. The postoperative complications were graded according to Clavien-Dindo classification in the UBM versus non-UBM groups. Grade I complications included postoperative hypoxemia requiring new home oxygen, narcotic-induced lethargy, delayed gastric emptying that resolved with bowel rest, 2 self-limiting small pneumothoraces, and 3 failed trial of urinary voiding requiring Foley catheter reinsertion. Grade II complications included 1 new-onset atrial fibrillation and 1 deep vein thrombosis, both requiring anticoagulation. Grade IIIa complications included 1 case of bilateral pleural effusion requiring thoracentesis and 4 cases of dysphagia requiring esophagogastroduodenoscopy (EGD). The authors believe that only 2 of the complications

[1] Zografakis et al. "Urinary Bladder Matrix Reinforcement for Laparoscopic Hiatal Hernia Repair". JSLS: Journal of the Society of Laparoendoscopic Surgeons. 22.2 (2018) 1-4.

[2] Howell et al. "Paraesophageal Hiatal Hernia Repair With Urinary Bladder Matrix Graft". JSLS: Journal of the Society of Laparoendoscopic Surgeons. 22.2 (2018) 1-6.

in the UBM group (dysphagia requiring EGD and dilation) could be deemed as mesh-related. There were no reports of reoperation. The results of the study demonstrate that there is no significant difference in post-operative complications, hospital length of stay, or 30-day readmissions between reinforced and non-reinforced patients.

Patient Demographics					
Sample Size		Mean Age	Age Range	Mean BMI	BMI Range
Total	56 (GSM) 65(non-GSM)				
Female	40(GSM) 42 (non-GSM)	63.9 (GSM) 54.3(non-GSM)	29–91 (GSM) 20–88 (non-GSM)	29.6 (GSM) 28.5 (non-GSM)	19–42 (GSM) 17.7–45 (non-GSM)
Male	16 (GSM) 23 (non-GSM)				

3. A retrospective clinical review includes 15 laparoscopic cases of hiatal hernia repair with primary crural repair with GSM 3-Layer reinforcement and fundoplication[3]. The defects were an average of 6 cm in diameter. The severity of each defect was not defined. There was an average follow up period of 3 years where follow up was conducted via upper gastrointestinal (GI) series, endoscopy, and assessments of subjective symptoms of gastroesophageal reflux disease (GERD).

Patient Demographics					
Sample Size		Mean Age	Age Range	Mean BMI	BMI Range
Total 15	F: 9 / M: 6	53	27 – 72	34	22 – 59

Each repair was successfully completed laparoscopically, through a 12 mm trocar without noted damage. One patient underwent endoscopic balloon dilation for post-operative dysphagia that resolved without further intervention. No other complications occurred. The GERD-health-related quality of life (HRQL) scores averaged 6 (range, 0–12, of a possible 50), indicating little reflux symptomatology. Nine of the fifteen cases completed a follow-up upper GI series; all 9 showed intact repairs. An upper endoscopy was performed in 8 patients and showed no recurrences. There were no recurrences or long- term complications, such as erosion, strictures, or infections.

4. Retrospective case results of a single fifty three years old female patient that underwent laparoscopic repair of a Type IV, 6 cm hiatal hernia defect with diaphragmatic crura reinforcement using GSM 6-Layer[4]. There were no intra operative and peri operative complications. An upper gastrointestinal (UGI) series was conducted at 6 months and there was additional follow up at 24months. The study reported a normal Upper gastrointestinal (UGI) series at a 6 month follow-up visit. In addition, the patient did not have clinical recurrence of the hernia during the 24 months follow-up period.

[3] Sasse, et al. "Hiatal Hernia Repair with Novel Biological Graft Reinforcement." JSLS: Journal of the Society of Laparoendoscopic Surgeons 20.2 (2016).

[4] Reznichenko "Extracellular Matrix Scaffold in Diaphragmatic Crura Reinforcement During Laparoscopic Repair of Large Hiatal Hernia." Journal of Surgery and Transplantation Science 4(1) (2016): 1018.

5. A Retrospective clinical review includes 11 patients who underwent laparoscopic repair of large hiatal hernias in a rural community hospital by a single surgeon[5]. All hernias were primary, there were no revisional surgeries. Fundoplication performed in ten out of eleven patients, using anterior Dor technique in eight patients, Nissen in one patient, and Toupet in one patient. Four of the eleven patients were reinforced with GSM. Of the 11 hernias there was one (1) type II hernia defect (non-GSM), eight (8) type III hernia defects (3 GSM, 5 non-GSM), and two (2) Type IV hernia defects (1 GSM: 1 non-GSM). All hernia defects were greater than 6cm with at least 40% of the stomach in the chest. A standard laparoscopic hiatal hernia repair was performed using different biologically-derived grafts for crural reinforcement.

Patient Demographics					
Sample Size	Mean Age	Age Range	Mean BMI	BMI Range	Avg. Defect Size
Total 11 F: 6 / M: 5	55.4 ± 8.7	42 – 68	32.5 ± 7.5	22 – 46	All: 7.7 cm x 6.4 cm UBM: 8 cm x 6.75 cm

Follow-up was conducted at 6-24 months. During follow-up, 7 patients (64%) underwent radiological evaluation 2 patients (18%) underwent esophagogastroscopy. Of the four patients that were reinforced GSM, one patient had shortness of breath that was resolved. There were no other early or late complications experienced with the four cases reinforced with GSM.

6. A Retrospective clinical review of 37 patients who underwent paraesophageal hiatal hernia repair by the same surgeon[6]. Of the 37 patients, 22 patients were reinforced with GSM 6-Layer over the crural repair and 15 patients did not receive reinforcement of the repair. Although Type I defects were excluded from this retrospective review, the size and severity of the defects were not defined. Patients returned for a one time follow up visit at a minimum of 12 months to assess for hernia recurrence both based on symptoms and radiographic evidence.

Patient Demographics				
Sample Size			Mean Age	Age Range
Total	22 (GSM) 15 (non-GSM)	Female 14(GSM) 11 (non-GSM)	69.8 ± 8.5 (GSM) 68.7 ± 9.9 (non-GSM)	50-87 (GSM) 48-83 (non-GSM)
		Male 8 (GSM) 4 (non-GSM)		

Recurrence occurred in 31.8% of patients in the GSM group and 46.7% non-reinforced group. Two GSM reinforced patients underwent re-operation due to recurrence. Secondary outcome measures were assessed including post-operative complications and quality of life. The percentage of patients that demonstrated radiographic evidence of recurrence was less in the GSM reinforced group when compared to the non-reinforced group, though this and other measures were not statistically significant. There were no differences in complications between the GSM reinforced group and the non-reinforced group.

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[5] Reznichenko "Different Biologic Grafts for Diaphragmatic Crura Reinforcement During Laparoscopic Repair of Large Hiatal Hernia: A Six-Year Single Surgeon Experience." Journal of Current Surgery 6.1 (2016): 6-13.

[6] Wang, C.Q. et al. “Symptomatic, Radiographic, and Quality of Life Outcomes After Paraesophageal Hernia Repair with MatriStem Surgical Matrix” The Society for Surgery of the Alimentary Tract 58th Annual Meeting Poster Presentation. Chicago, IL.

	ACell, Inc. Gentrix® Surgical Matrix Gentrix® Surgical Matrix Hiatal	**ACell, Inc.** Gentrix™ Surgical Matrix 2-Layer, 3- Layer, 6-Layer, 8-Layer
510(k) No.	TBD	K162554
Device Class	Class II	Class II
Product Code	FTM, OXH, OWV	FTM, OXH
Classification	ECM, Surgical Mesh	ECM, Surgical Mesh
Intended Use / Indications for Use	Gentrix® Surgical Matrix (3-layer) is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological, gastroenterological, or plastic & reconstructive surgery. Reinforcement of soft tissue within urological, gastroenterological, and plastic & reconstructive surgery includes, but is not limited to, the following open or laparoscopic procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. The Gentrix® Surgical Matrix (3-layer) minimizes tissue attachment to the device in case of direct contact with viscera. Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Hiatal (6-layer and 8-Layer) are intended for implantation to reinforce soft tissue where weakness exists in patients requiring gastroenterological or plastic & reconstructive surgery. Reinforcement of soft tissue within gastroenterological and plastic & reconstructive surgery includes, but is not limited to, the following open or laparoscopic procedures: hernia (e.g.: hiatal/diaphragmatic) and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. The Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Hiatal (6-layer and 8- Layer) minimizes tissue attachment to the device in case of direct contact with viscera.	Gentrix™ Surgical Matrix 2-layer and 3- Layer are intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological, gastroenterological, or plastic & reconstructive surgery. Reinforcement of soft tissue within urological, gastroenterological, and plastic & reconstructive surgery includes, but is not limited to, the following procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair. Gentrix™ Surgical Matrix 6-layer and 8-Layer are intended for implantation to reinforce soft tissue where weakness exists in patients requiring gastroenterological or plastic & reconstructive surgery. Reinforcement of soft tissue within gastroenterological and plastic & reconstructive surgery includes, but is not limited to, the following procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair.
Material Source	Porcine Urinary Bladder	Porcine Urinary Bladder
Material Type	Collagen, Extracellular Matrix	Collagen, Extracellular Matrix
Resorbable	Yes	Yes
Shape	Rectangular and U-Shape	Rectangular
Nominal Sizes	Up to 10 cm x 15 cm	Up to 10 cm x 15 cm
Reusable	Single Use Device	Single Use Device
Packaging	Dual Foil:PET Pouch System	Dual Foil:PET Pouch System
Sterilization	electron beam irradiation	electron beam irradiation

Conclusions

The Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Hiatal device configurations have the same intended use as the predicate device, as demonstrated by the preclinical animal studies and clinical data from literature used to support the safety and effectiveness for the new labeled use of hiatal hernia repair. In addition, the subject device has the equivalent technological characteristics as the predicate device. Therefore, the Gentrix® Surgical Matrix and Gentrix® Surgical Matrix Hiatal device configurations are substantially equivalent to the cleared predicate devices.