Substantial Equivalence Table

	Subject Device	Predicate Devices									
	Collagen Scaffold (CS) ReGen Biologics	Restore® Orthobiologic Soft Tissue Implant DePuy, Inc.	BioBlanket Surgical Mesh Kensey Nash Corp	SIS Fistula Plug Cook Biotech Inc	TissueMend, OrthoMend TEI Biosciences	Surgisis Cook Biotech Inc	Permacol, ZCR Graft Tissue Science Laboratories	Optimesh Spineology, Inc.	CuffPatch Organogenesis	Sportmesh Artimplant AB	Marlex Mesh Davol
K Number	K053621	K031969 K001738 K982330	K043259 K041923	K050337	K031188 K051766	K974540 K980431 K992159 K022044 K034039 K050246	K992556 K013625 K021056 K043366 K050355	K014200	K042809	K052830	Pre-Amendment
Class	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Class II	Class II	NA
Regulation	878.3300	878.3300	878.3300	878.3300	878.3300	878.3300	878.3300	878.3300	878.3300	878.3300	NA
Common Name	Surgical Mesh	Surgical Mesh	Surgical Mesh	Surgical Mesh	Surgical Mesh	Surgical Mesh	Surgical Mesh	Mesh, Metal	Surgical Mesh	Surgical Mesh	Surgical Mesh
Product Code	FTM	FTM	FTM	FTM	FTL	FTM, FTL	FTM, FTL	EZX	FTM	FTM	NA
Intended Use	[redacted]	**For use in general surgical procedures for reinforcement of soft tissue where weakness exists.** In addition, is intended for use in specific application of reinforcement of soft tissues which are repaired by suture or suture anchors, during rotator cuff repair surgery. Reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue **Not intended to replace normal body structure or provide the full mechanical strength to repair** rotator cuff.	**For use in general surgical procedures for reinforcement and repair of soft tissue where weakness exists, including but not limited to,** defects of the thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, **hernias,** suture line reinforcement	For **implantation to reinforce soft tissue** where a rolled configuration is required, for repair of anal, rectal and enterocutaneous fistulas.	**For surgical implantation to reinforce soft tissue where weakness** exists and for the repair of damaged or ruptured soft tissue membranes. Intended to reinforce soft tissues that are repaired by suture or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patella, Achilles, biceps, quadriceps, or other tendons.	**For implantation to reinforce soft tissue where weakness exists** in patients requiring soft tissue repair or reinforcement. Indications include plastic and reconstructive surgery (inlcuding the face and head), **repair of a hernia or body wall defect.** Includes use in the urological, gynecological, and gastroenterological anatomy, including but not limited to the following procedures: pubourethral support, urethral and vaginal	**For use as a soft tissue patch to reinforce soft tissue where weakness exists** and for the surgical repair of damaged or ruptured soft tissue membranes. Specifically indicated for repair of abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical, parastomal and incisional **hernias;** colon, rectal, urethral and vaginal prolapse; muscle flap reinforcement; reconstruction of the pelvic floor, and procedures such as	Intended to maintain the relative position of bone graft material (such as autograft or allograft) within a vertebral body defect (eg. tumor) that does not impact the stability of the vertebral body and does not include the vertebral endplates.	For **reinforcement of soft tissues** repaired by sutures or suture anchors, during tendon repair surgery, including reinforcement of rotator cuff, patella, Achilles, biceps, quadriceps, and other tendons. Sutures used to repair the tear and sutures or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair. **Reinforces soft**	**For use in general surgical procedures for reinforcement of soft tissue where weakness exists.** Also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery. **Not intended to replace normal body structure or provide the full mechanical strength to**	**For use in the intra-articular space of the knee, including use in the repair of defects in the medial and lateral femoral condyles** as well as the patella

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	.	Sutures to repair the tear and sutures or bone anchors to reattach the tissue to the bone provide mechanical strength for rotator cuff repair. **Reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.**	and reconstructive procedures. Also intended for reinforcement of soft tissues which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery.		**Not intended to replace normal body structure or provide the full mechanical strength** to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear and sutures or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair. **Reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own tissues.**	prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, and sacrocolpo-suspension. By providing urethral support, may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency. Also includes use of a staple line reinforcement during various surgical procedures, including lung resection and gastric bypass.	sacrocolpo-suspension and urethral sling. Indications also include **soft tissue repair or reinforcement** in plastic and reconstructive surgery of the face and head; and reinforcement of the soft tissues which are repaired by sutures or suture anchors, limited to the supraspinatus during rotator cuff repair surgery.		**tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.**	support the rotator cuff. Sutures used to repair the tear and sutures or bone anchors used to attach the tissue to the bone provide mechanical strength for the tendon repair. **Reinforces soft tissue and provides a degradable scaffold that is incorporated in the patient's own tissue.**	
Materials		Porcine small intestine submucosa (SIS) comprised predominantly of water and types I and III collagen with small amounts of glycosaminoglycans	Single layer porous, cross-linked collagen	Porcine small intestine submucosa (SIS) comprised predominantly of water and types I and III collagen with small amounts of glycosamino-glycans	Collagen	Porcine small intestine submucosa (SIS) comprised predominantly of water and types I and III collagen with small amounts of glycosamino-glycans	Acellular crosslinked porcine dermal collagen	Polyethylene Terephthalate (PET)	Laminated sheets of acellular porcine-derived collagen from the intestine	Artelon fiber knit mesh (poly urethane urea)	Polypropylene mesh

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Bioabsorbable		Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Degrades; 50% resorption in 6 years	No
Form		Disc, 10 plys of SIS	Sheet/Pad	Pre-formed shape of tapered solid cylinder	Sheet	Sheets of various sizes; pre-shaped forms depending on application	Sheets of various sizes; pre-shaped forms depending on application	Three dimensional pouch	Sheets of various sizes	Sheet	Sheet
Size		Nominal diameter 63 mm, 10 ply SIS	5x5cm to 5x10cm 1.0±0.25mm thickness	1 to 7 mm in diameter, 10cm in length	Not Specified	Up to 20x20cm and 1 mm thickness	Not Specified	Not Specified	Not Specified	~0.8mm thickness	Not Specified
Suture pullout strength		3.69±0.90lb_f	Not Specified	11.21±4.13lb_f	7.79±0.81lb_f	0.85 to 5.74lb_f	Not Specified	Not Specified	Not Specified	>30N	Not Specified
Customized Use		SAME	SAME	SAME	SAME	SAME	SAME	Deployable for minimally invasive implantation in vertebral body	SAME	SAME	SAME