

Predicate Resorbable Surgical Meshes (21CFR878.3300) with New Indication(s)

510(k)	INDICATIONS	COMMENTS
K923657 Bio-Vascular Supple Peri-Guard	For repair of hernias and other intra-abdominal soft tissue defect or deficiency	No 510k summary; Purged 510k
K940205 Bio-Vascular Peri-Strips	For surgical stapling of lung tissue, gastric stapling, rectal and vaginal prolapse, urethral sling, reconstruction of the pelvic floor, and hernia or defects of the diaphragm, thoracic and abdominal wall	No 510k summary; Purged 510k
K942911 Glycar Tissue Repair Patch	For repair of hernias and other intra-abdominal soft tissue defect or deficiency	No 510k summary; Purged 510k; Bio-Vascular Peri-Guard device used as predicate
K954665 Glycar Staple Strips	For surgical stapling of lung tissue, gastric stapling, rectal and vaginal prolapse, urethral sling, reconstruction of the pelvic floor, and hernia or defects of the diaphragm, thoracic and abdominal wall	No 510k summary; Purged 510k; Bio-Vascular Peri-Strips device used as predicate
K961440 Fusion Medical RapidSeal Patch	Reinforces soft tissue of the lung thereby sealing or reducing air leaks that occur during pulmonary surgery	Evaluation in 26 patient open-labeled study with endpoint of leak closure. Results showed out of 52 leaks, 96% were successfully closed.
K963226 Boston Scientific Surgical Fabrics (aka Protegen Sling)	Intended to reinforce soft tissue where weakness exists for the urological, gynecological and gastroenterological anatomy inclusive but not limited to the following procedures: pubourethral support , urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support , and sacro-colposuspension .	Tested and compared to the predicate devices (synthetic meshes and Peri-Guard mesh) <i>Note: Device was removed from the market in 1999 due to high incidence of erosion</i>
K964857 Fusion Medical RapidSeal Patch	Provides a temporary matrix during the natural tissue repair process, resulting in the additional benefit of hemostatic tamponade	Clinical evaluation in 48 patients during “pre-commercial phase.” Results were no patch-related complications, and patch was capable of successfully reducing or sealing air leaks intraoperatively. Note: no clinical data to support benefit of tamponade, only animal data.

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K980483 Mentor Suspend Sling	Intended to reinforce soft tissue where weakness exists in the urological anatomy inclusive of the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension. Intended for the treatment of female urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.	Comprised of segmented polyether urea urethane elastomer with an anti-bacterial coating. Tested for biocompatibility and suture pull strength. Cited predicates were the GoreTex Tissue Reinforcement Patch and the Protegen Sling.
K983162 Bio-Vascular Peri-Guard and Peri-Strips	For repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias). For use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. To reinforce staple lines during lung resections including pneumonectomy, pneumoreduction, pneumectomy, lobectomies, segmentectomies (segmental resections), wedge resection, bullectomies, blebectomies, bronchial resections, and other lung incisions and excisions of lung and bronchus.	No performance data cited other than cross-linked treatment with 1M NaOH
K001738 DePuy Restore	For use in general surgical procedures for reinforcement of soft tissue where weakness exists. The device is intended to act as a resorbable scaffold that initially has sufficient strength to assist with a soft tissue repair, but then resorbs and is replaced by the patient's own tissue. In addition, the implant is intended for use in the specific application of reinforcement of the soft tissues which repaired by suture or suture anchors limited to the supraspinatus during rotator cuff repair surgery.	Feasibility study 5 patients followed for 3 months, with several surgeon letters of support (from purged 510k)
K021160 Carbon Medical Technologies Dermatrix	Intended for use in the treatment of hernias where the connective tissue has ruptured or for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support including urethral slings, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, and sacro-colposuspension.	510k Summary cites bench testing and "numerous clinical experiences"
K024199 OsteoBiologics IMMIX Thin Film	For use wherever temporary wound support is required , to reinforce soft tissue where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing, or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.	Bench tested cited to "support its suitability for use in a clinical situation"

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K031969 DePuy Restore	For use in general surgical procedures for reinforcement of soft tissue where weakness exists. In addition, the implant is intended for use in the specific application of reinforcement of the soft tissues, which are repaired by suture or suture anchors, during rotator cuff repair surgery. The Restore Implant is not intended to replace normal body structure or provide the full mechanical strength to repair the rotator cuff. Sutures to repair the tear and sutures or bone anchors to reattach the tissue to the bone provide mechanical strength for the rotator cuff repair. The Restore Implant reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.	Clinical data "replaced by the patient's own tissue"
K030782 Gore Seamguard Staple Line Reinforcement	For surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. Can be used for reinforcement of staple lines during lung resection and for reinforcement of gastric staple lines during bariatric surgical procedures of gastric bypass and gastric banding.	Device "integrity testing" performed
K03337 Ethicon UltraPro Mesh	For the repair of hernias and other abdominal fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.	510k summary states: "comparison to other commercialized surgical meshes indicates equivalency in clinical performance." "Additionally, animal testing demonstrated that UltraPro would achieve good tissue ingrowth."
K040364 Porex Surgical Medpore Surgical Implant	For non-weight bearing applications of craniofacial reconstruction/cosmetic surgery and repair of craniofacial trauma	No testing cited
K042809 Organogenesis CuffPatch	For reinforcement of soft tissues repaired by sutures or suture anchors, during tendon repair surgery including reinforcement of rotator cuff, patella, Achilles, biceps, quadriceps or other tendons. Not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff rotator cuff, patella, 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. CuffPatch surgical mesh reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.	510k summary states bench testing indicates suitability for its intended clinical applications
K043259 Kensey Nash BioBlanket	For use in general surgical procedures for the 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 and reconstructive procedures. The device is also intended for reinforcement of the soft tissue which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery.	510k summary cites biocompatibility, integrity, in vitro and in vivo performance testing

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K043388 Pegasus Biologics OrthoAdapt Surgical Mesh	For implantation to reinforce soft tissue including but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement, and reconstructive procedures. The device is also intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patella, Achilles, biceps, quadriceps, or other tendons. OrthoAdapt is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patella, Achilles, biceps, quadriceps or other tendons. Suture, 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.	No 510k summary – statement only
K050337 Cook Biotech SIS Fistula Plug	For implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal, and enterocutaneous fistulas.	Clinical experience in ~25 patients with approximately 3 months follow-up to show fistula closure.
K050445 AMS Collagen Dermal Matrix	For use in the treatment of hernias where the connective tissue has ruptured or for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support including urethral slings, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, sacral colposuspension and reinforcement in the repair of Peyronie's disease . By providing pubourethral support, the AMS collagen dermal matrix may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.	510k summary cites bench testing
K051701 Ethicon Vicryl Mesh Bag	For use wherever temporary wound or solid organ support is required (kidney, liver, spleen)	No testing cited in 510k summary; Vicryl mesh used as predicate
K061892 Cryolife ProPatch Soft Tissue Repair Matrix	For implantation to reinforce soft tissues where weakness exists, including but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement, and reconstructive procedures. The device is also intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patella, Achilles, biceps, quadriceps, or other tendons. Device is 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. Suture, 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. The device reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.	510k cites bench testing performed