



Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2028

Number of Requests: 53

Technology Name

Generic Name: N/A

Trade Name: CARA System

Applicant Name: Cara Medical Ltd.

Application Pathway: Traditional

Brief Description of the Technology:

The CARA System identifies, from anatomical landmarks marked manually on multiplanar reformatted views of computed tomography angiography (CTA) by a trained reader and confirmed by the physician, the position of the individual patient's cardiac conduction axis, and from it diagnoses, before the procedure, the patient's susceptibility to iatrogenic



Technology Name

Generic Name: N/A

Trade Name: BriefCase-Triage CARE Triage Chest X-ray (CXR)

Applicant Name: Aidoc Medical Ltd., Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

BriefCase-Triage: CARE (Clinical AI Reasoning Engine) Triage CXR is a single-model, 2-clinical indication radiological triage device. Its purpose is to flag and communicate suspected positive findings of clinically actionable, time-sensitive conditions in the chest region.



Technology Name

Generic Name: Tebipenem pivoxil. The active ingredient is supplied as tebipenem pivoxil hydrobromide.

Trade Name: Utebzi

Applicant Name: GSK

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Utebzi (tebipenem pivoxil) is the first and only FDA-approved oral carbapenem antibacterial. It is indicated for adults with complicated urinary tract infections (cUTI), including pyelonephritis, caused by designated susceptible bacteria, who have limited or no alternative oral treatment options.



Technology Name

Generic Name: size-adjustable synthetic pulmonary valve

Trade Name: AUTUS size-adjustable valve

Applicant Name: Edwards Lifesciences LLC

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

AUTUS size-adjustable valve is the only surgical pulmonary valve designed specifically for growing children born with pulmonary valve disease. This synthetic pulmonary valve is expandable to account for somatic growth via transcatheter procedure.



Technology Name

Generic Name: Not Applicable

Trade Name: TELLTALE Electrosurgical Guidewire System

Applicant Name: TELLTALE LLC wholly owned subsidiary of Transmural Systems LLC

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

TELLTALE is a single-use electrosurgical guidewire system, with dedicated guiding catheters and procedure accessories, used immediately before TAVR to lacerate a native or bioprosthetic aortic valve leaflet with radiofrequency energy so that the leaflet cannot obstruct a coronary artery once the new valve is deployed.



Technology Name

Generic Name: Pattern Pneumonia

Trade Name: Pattern Pneumonia ID/AST Panel

Applicant Name: Pattern Bioscience

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Pattern® System is an automated in vitro diagnostic platform that isolates single bacterial cells in picoliter-scale droplets and measures real-time metabolic activity of individual bacterial cells. The system is capable of reporting pathogen detection, organism identification, semi-quantification, and phenotypic AST in hours.



Technology Name

Generic Name: cefepime and zidebactam

Trade Name: ZAYNICH

Applicant Name: Wockhardt Suisse USA LLC

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Zaynich (cefepime and zidebactam) is an intravenous beta-lactam/betalactam enhancer and inhibitor combination antibiotic for the treatment of patients with serious/life-threatening infections caused by Multi-Drug Resistant (MDR) and Extensively-Drug-Resistant (XDR) Gram-negative bacteria.



Technology Name

Generic Name: Onyx

Trade Name: iFuse Granite Onyx Implant System

Applicant Name: SI-BONE, Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Onyx is a Breakthrough Device designated pedicle implant designed to improve fixation in spinal fusions. The Onyx design integrates anatomy-specific threads with a microporous trabecular lattice surface to promote osseointegration and reduce loosening, toggle, and implant failure, which can affect up to 39% of spinal fusion cases.



Technology Name

Generic Name: Radiological computer aided triage and notification software

Trade Name: a2z-Abdo-Triage

Applicant Name: a2z Radiology AI Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

a2z-Abdo-Triage is a single-device, ten-finding radiological computer-aided triage and notification software for abdominopelvic CT. It flags and communicates suspected positive cases of ten specified abdominopelvic findings, in parallel with standard-of-care interpretation, to support worklist prioritization.



Technology Name

Trade Name: ALGO

Applicant Name: Von Vascular, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

ALGO is a computer-controlled aspiration pump system designed for use with compatible aspiration catheters during mechanical thrombectomy. It provides conventional continuous aspiration (SMARTstatic) and a proprietary Adaptive Pulsatile Aspiration (APA) modes that modulates pressure at the catheter tip.



Technology Name

Generic Name: Antibiotic Coated Metallic Intramedullary (IM) Nail/Rod

Trade Name: Tibial Nail PROtect

Applicant Name: DePuy Synthes

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Tibial Nail PROtect is an antibiotic coated nail for tibia shaft fractures designed to reduce the risk of fracture related infection (FRI).



Technology Name

Generic Name: Talar Replacement Device

Trade Name: 4WEB Talus Replacement Type 4 (TRT4)

Applicant Name: 4WEB Medical, Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The 4WEB Talus Replacement Type 4 (TRT4) device is a patient-matched cobalt-chromium implant designed to replace the patient's native talus, articulate with the Stryker Total Ankle Replacement systems, and immobilize the subtalar joint. The device is patient-matched using CT scans of a patient's anatomy and 3D modeling software.



Technology Name

Generic Name: Peripheral Stent

Trade Name: Micro Medical Solutions MicroStent and the MicroStent XL Peripheral Vascular Stent System

Applicant Name: Micro Medical Solutions

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The MicroStent Peripheral Vascular Stent System is indicated for use in infrapopliteal arteries ranging in diameter from 2.5 to 4.5 mm following a suboptimal acute result of endovascular treatment (flow-limiting dissection/vessel perforation, acute elastic recoil, or residual stenosis of at least 30%).



Technology Name

Generic Name: Non-invasive diaphragm monitoring system using ultrasound for assessment of diaphragm movement

Trade Name: Respinor DXT®

Applicant Name: RESPINOR AS

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

RESPINOR DXT is a prescription, non-invasive, ultrasound-based device that provides operator-independent, continuous monitoring (up to 150 minutes per exam) of diaphragm movement in patients ≥ 18 years of age in the ICU to identify patients who are at increased risk of extubation failure during the weaning process from mechanical ventilation.



Technology Name

Generic Name: AI-based clinical deterioration early warning software, classification - Adjunctive Predictive Cardiovascular Indicator (21 CFR 870.2210)

Trade Name: eCARTv5 Clinical Deterioration Suite

Applicant Name: AgileMD, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

eCART is an FDA-cleared clinical decision support software system for hospitalized adult ward patients which uses a gradient-boosted machine-learning model to analyze EHR data and predict impending clinical deterioration. The tool prompts clinicians to follow standardized workflows in the evaluation and treatment of at-risk patients.



Technology Name

Trade Name: xBar System

Applicant Name: Exero Medical

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

xBar is a monitoring device that supports the early detection of anastomotic leaks following colorectal surgery. It consists of an electrode array embedded in a standard surgical drain, an electronic recording system that relays electrophysiological data to a data processing cloud, and an web application that shares information with clinical users.



Technology Name

Generic Name: Anitocabtagene autoleucel (anito-cel)

Applicant Name: Kite Pharma, a Gilead company

Application Pathway: Traditional

Brief Description of the Technology:

Anito-cel, under review for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM), is an autologous B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T-cell therapy. It features a novel, fast off-rate D-Domain binder with high cell surface T cell expression and minimal tonic signaling.



Technology Name

Generic Name: VBX Device or VBX Stent Graft

Trade Name: GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

Applicant Name: W.L. Gore & Associates, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX) is an endoprosthesis that, upon FDA approval, will be indicated as a bridging stent to maintain visceral artery perfusion in fenestrated or branched endovascular abdominal aortic aneurysm repair with appropriately sized fenestrations or branches, as specified in the Instructions for Use



Technology Name

Generic Name: Drug-eluting percutaneous transluminal coronary angioplasty catheter

Trade Name: SELUTION SLR™ 014 PTCA Drug-Eluting Balloon

Applicant Name: Cordis

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The SELUTION SLR™ 014 PTCA Drug-Eluting Balloon is a sustained limus release drug-eluting percutaneous transluminal coronary angioplasty (PTCA) balloon catheter. It is used to improve myocardial perfusion when treating in-stent restenosis of the heart.



Technology Name

Generic Name: VT cryoablation system

Trade Name: vCLAS™ Ventricular Ablation System

Applicant Name: Adagio Medical

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The vCLAS™ Ventricular Ablation System, also referred to as the vCLAS Ventricular Ablation System, is intended to create linear and focal lesions to cardiac structures in the ventricles with cryoablation.



Technology Name

Generic Name: The SonoClear System

Trade Name: The SonoClear® System

Applicant Name: SonoClear AS

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The SonoClear® System is an ultrasound acoustic coupling fluid for intracranial ultrasound procedures used in intracranial ultrasound-guided surgical tumor resection. It improves the ability to differentiate tumor tissue from surrounding brain tissue, providing surgeons with more accuracy in real time, and allowing more precise resections.



Technology Name

Generic Name: KidneyPod

Trade Name: KidneyPod™

Applicant Name: Diatiro

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

KidneyPod™ is a sterile, single use add on device intended to provide hypothermic treatment by continuing static hypothermic preservation of a donor kidney during vascular anastomosis in recipients undergoing kidney transplantation to treat End Stage Renal Disease.



Technology Name

Generic Name: Patient-Specific Reverse Total Shoulder

Trade Name: Veritas Reverse Total Shoulder System

Applicant Name: restor3d

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Veritas™ is a reverse total shoulder arthroplasty (rTSA) system whose glenoid baseplate, fixation trajectories, and instruments are designed from each patient's CT and additively manufactured to match their glenoid. The porous, patient-specific baseplate is paired with standard restor3d screws, glenosphere, humeral stem, and polyethylene insert.



Technology Name

Generic Name: Implanted sub-scalp continuous bilateral electroencephalography monitoring system

Trade Name: The Minder® System

Applicant Name: Epiminder USA, Inc

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Minder System is an implantable continuous EEG monitoring (iCEM) system designed for long-term bilateral sub-scalp electroencephalographic recording in adult patients with drug-resistant epilepsy. The system consists of four principal components (implant, wearable, app, cloud), which work together for remote continuous EEG monitoring.



Technology Name

Generic Name: Implanted Brain Stimulator for Epilepsy

Trade Name: The RNS® System

Applicant Name: Neuropace

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The RNS® System is intended for responsive neurostimulation as an adjunctive therapy in reducing the frequency of generalized tonic-clonic seizures in individuals who have drug-resistant idiopathic generalized epilepsy.



Technology Name

Generic Name: Opioid sparing, settable, adhesive bone putty

Trade Name: Montage CT

Applicant Name: Manufacturer (Abyrx, Inc.)

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Montage CT is a hardening, implantable bone putty consisting of calcium phosphate, absorbable polymer, and vitamin E acetate.



Technology Name

Generic Name: Transcatheter artery revascularization with integrated embolic protection and reservoir based flow-reversal system.

Trade Name: Neuroguard IEP™ Direct System

Applicant Name: Contego Medical

Application Pathway: Traditional

Brief Description of the Technology:

Neuroguard IEP Direct is the first and only TCAR system with integrated distal embolic protection and reservoir-based flow reversal system, designed to address residual stroke risk. Its 3-in-1 stent, integrated-filter and post-dilation balloon provide targeted microembolic protection during stenting and post-dilation, in addition to flow reversal.



Technology Name

Generic Name: ifezuntirgene inilparvovec

Applicant Name: uniQure biopharma B.V. (the manufacturer)

Application Pathway: Traditional

Brief Description of the Technology:

Ifezuntirgene inilparvovec is an adeno-associated virus (AAV) vector-based investigational gene therapy, administered in a single neurosurgical procedure, that is designed to target and reduce the production of the toxic Huntingtin (HTT) protein responsible for Huntington's disease in the brain.



Technology Name

Generic Name: Software device for estimation of cardiac pressures

Trade Name: PCWP Analysis Software™

Applicant Name: Cardiosense

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

PCWP Analysis Software is a machine learning-based software that noninvasively estimates pulmonary capillary wedge pressure (PCWP) and identifies whether the PCWP is above or below 18mmHg. It is indicated for adult patients diagnosed with heart failure with reduced ejection fraction (HFrEF) and NYHA Functional Class II, III, IV symptoms.



Technology Name

Generic Name: Lumbar Total Joint Replacement (LTJR)

Trade Name: MOTUS

Applicant Name: 3Spine, Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The MOTUS Total Joint Replacement System is a spinal implant system intended to replace the function of both a damaged lumbar intervertebral disc and facet joint. The MOTUS Total Joint Replacement device is a permanent implant that is intended to maintain the ability to move at the affected level after treatment.



Technology Name

Generic Name: n/a

Trade Name: KLS Martin L1 Thoracic PEEK XL Plate System

Applicant Name: KLS-Martin LP

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

PEEK XL is an open plate design made of PEEK with a modulus of elasticity similar to bone. It offers three plate sizes for thoracic defect reconstruction, can be cut intraoperatively to fit patient anatomy, includes holes for screw fixation to stabilize the thorax in critical chest wall reconstructions, and is supplied sterile.



Technology Name

Generic Name: etuvetidigene autotemcel

Trade Name: WASKYRA®

Applicant Name: Orphan Therapies

Application Pathway: Traditional

Brief Description of the Technology:

WASKYRA is an autologous hematopoietic stem cell-based gene therapy. CD34+ cells are enriched and transduced ex vivo with a replication-incompetent, self-inactivating (SIN) human immunodeficiency virus-1 (HIV1)-based lentiviral vector carrying the Wiskott-Aldrich syndrome (WAS) gene sequence under control of the human WAS promoter for expression.



Technology Name

Generic Name: bentracimab

Trade Name: Not yet established

Applicant Name: BTG International, Inc. (a SERB company)

Application Pathway: Traditional

Brief Description of the Technology:

Bentracimab is a novel, investigational, human monoclonal antibody fragment (Fab) designed to reverse the antiplatelet activity of ticagrelor, an oral P2Y₁₂ platelet receptor inhibitor, in patients requiring urgent surgery or invasive procedure and in patients experiencing major bleeding, in whom ticagrelor impairs normal hemostasis.



Technology Name

Generic Name: VCFix

Trade Name: VCFix Spinal System

Applicant Name: Amber Implants Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

VCFix is a vertebral reconstruction technology designed to reduce vertebral compression fractures, restore vertebral body anatomy, and provide internal structural support prior to cement augmentation. It is intended for osteoporotic, traumatic, and tumor-related vertebral fractures and provides controlled vertebral body expansion and stabilization



Technology Name

Generic Name: Surgical nerve stimulator/locator (21 CFR 874.1820, product codes PDQ and ETN) with mechanomyographic nerve-response threshold measurement.

Trade Name: Neuraltix iD3 System

Applicant Name: Neuraltix, LLC

Application Pathway: Traditional

Brief Description of the Technology:

The iD3 is a surgical nerve stimulator that automatically finds a nerve root's mechanomyographic (MMG) threshold, the lowest current that elicits a muscle response, and keeps adjusting as the probe moves. Compressed roots generally need more current, so surgeons weigh each root's values with the anatomy to judge whether decompression is complete.



Technology Name

Generic Name: doxycycline hyclate

Trade Name: D-PLEX

Applicant Name: Azurity Pharmaceuticals

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

D-PLEX delivers broad-spectrum antibiotic protection when applied directly at the surgical wound through continuous, controlled release for 30 days. It reduces surgical site infections and infection-related complications and improves clinical outcomes during the postoperative recovery period.



Technology Name

Generic Name: Isoflurane (drug component of combination product)

Trade Name: Sedana Medical® ACD Delivery System with IZOZED™

Applicant Name: Sedana Medical AB (publ)

Application Pathway: Traditional

Brief Description of the Technology:

Sedana Medical® ACD Delivery System with IZOZED™ (the new technology) is a drug-device combination product enabling the inhaled isoflurane sedation of mechanically ventilated adult ICU patients. The new technology consists of a disposable drug delivery device (the Sedana Medical® ACD), associated disposable components and the drug (IZOZED™).



Technology Name

Generic Name: pritelivir

Applicant Name: Veloxis Pharmaceuticals, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Pritelivir is not yet approved; the anticipated approval date is 10/13/2026. Pritelivir is an oral, herpes simplex virus (HSV) antiviral agent targeting the helicase-primase complex intended for treatment of HSV lesions in immunocompromised adults that are refractory, with or without resistance, to acyclovir, valacyclovir, or famciclovir.



Technology Name

Generic Name: DeepView AI System

Trade Name: DeepView AI™ System

Applicant Name: Spectral AI, Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The DeepView AI System with AI Burn software acquires and analyzes images using artificial intelligence to detect deep partial thickness and full thickness burns. It provides segmentation and highlighting of specific areas in a burn wound that are unlikely to heal within 21 days with conservative treatment alone.



Technology Name

Generic Name: DynamX SECBS

Trade Name: DynamX® Sirolimus Eluting Coronary Bioadaptor System SECBS

Applicant Name: Elixir Medical Corporation

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The DynamX SECBS is a device for the treatment of CAD, designed to improve coronary luminal diameter and enable restoration of hemodynamic modulation within the treated vessel segment (pulsatility/compliance), as the primary device mode of action. Sirolimus is incorporated as the pharmacological component to reduce the vessel response to injury.



Technology Name

Generic Name: Diagnostic intracerebral catheter

Trade Name: nyteOWL nOCT Imaging Probe

Applicant Name: Spryte Medical

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Spryte Medical nOCT Imaging System with nyteOWL nOCT Imaging Probe is intended for intravascular diagnostic imaging of the neurovascular arteries and indicated for patients undergoing endovascular treatment procedures for intracranial aneurysms.



Technology Name

Generic Name: Biodegradable biliary and pancreatic stent

Trade Name: ARCHIMEDES™ Biodegradable Stent

Applicant Name: Q3 Medical USA LLC

Application Pathway: Traditional

Brief Description of the Technology:

ARCHIMEDES™ Medium is a single-use, biodegradable polymeric stent designed to provide temporary drainage and support of the biliary or pancreatic ducts. The stent maintains ductal patency during the intended treatment period and then degrades in situ through hydrolysis, eliminating the need for a subsequent procedure to remove the stent.



Technology Name

Generic Name: Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq

Trade Name: TREGZI™

Applicant Name: Orca Biosystems, Inc. (Orca Bio)

Application Pathway: Traditional

Brief Description of the Technology:

TREGZI is an allogeneic regulatory T cell-based immunotherapy with hematopoietic stem and progenitor cells and T cells indicated for use in matched donor alloHSCT with myeloablative preparative regimen, for hematopoietic and immunologic reconstitution and to improve cGVHD-free survival, in the treatment of adults with hematological malignancies.



Technology Name

Generic Name: Autologous cutaneous multicellular units

Trade Name: SkinTE

Applicant Name: PolarityBio

Application Pathway: Traditional

Brief Description of the Technology:

SkinTE is an autologous cutaneous multicellular therapy anticipated for the treatment of adult patients with Wagner grade 1 diabetic foot ulcers (DFU) in conjunction with standard of care (SOC).



Technology Name

Generic Name: Drug-Eluting Bioresorbable Vascular Scaffold

Trade Name: MOTIV Sirolimus-Eluting Bioresorbable Vascular Scaffold

Applicant Name: REVA Medical, LLC

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The MOTIV Bioresorbable Scaffold is a drug-eluting resorbable scaffold (DRS) designed specifically for use in treating de novo or restenotic lesions in native infrapopliteal arteries due to peripheral artery disease.



Technology Name

Generic Name: Rezafungin

Trade Name: Rezzayo

Applicant Name: CorMedix, Inc

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? No

Brief Description of the Technology:

REZZAYO is an echinocandin antifungal indicated in adults and pediatric patients 12 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Rezzayo has completed a Phase III trials prophylaxis of fungal infections in adult patients undergoing allogeneic blood and marrow transplant



Technology Name

Generic Name: ExaStim System

Trade Name: ExaStim® Stimulation System

Applicant Name: ANEUVO

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

ANEUVO's ExaStim platform uses non-invasive electrical stimulation to re-engage the nervous system after spinal cord injury in order to re-activate neural circuitries, helping to restore lost movement, strength, and body function.



Technology Name

Generic Name: Queen of Hearts

Trade Name: Queen of Hearts™ (ACS AI ECG Model)

Applicant Name: Powerful Medical Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

Queen of Hearts™ is AI software analyzing 12-lead resting ECGs of adults (22+) with suspected ACS. An adjunctive decision support tool, it identifies ECG findings suggestive of urgent ACS, which can include STEMI and STEMI equivalents, and notifies clinicians to support urgent cardiology consult and potentially early cardiac catheterization.



Technology Name

Generic Name: imlifidase

Applicant Name: Hansa Biopharma

Application Pathway: Traditional

Brief Description of the Technology:

Imlifidase is a cysteine protease enzyme that reduces donor-specific antibodies in highly sensitized patients to levels consistent with crossmatch conversion within hours, thereby enabling HLA-incompatible transplantation.



Technology Name

Generic Name: External ventricular drain catheter flushing device (component of a cerebrospinal fluid drainage system anticipated product code JXG, 21 CFR 882.5550)

Trade Name: ReFlow Guardian EVD Catheter Clearance System. Two configurations REF A024, 0.5 mL and REF A035, 1.0 mL

Applicant Name: Anuncia Medical Inc.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The ReFlow® Guardian™ EVD Catheter Clearance System is a single-patient-use, manually actuated device placed in line between an external ventricular drain (EVD) catheter and CSF collection bag. When compressed, it sends a retrograde pulse of the patient's own CSF to restore or maintain catheter flow without opening the closed system.



Technology Name

Generic Name: Implantable cerebrospinal fluid shunt catheter clearance device (flusher) (component of a CSF shunt system, 21 CFR 882.5550, product code JXG)

Trade Name: ReFlow® Guardian™ PPx Catheter Clearance System (Guardian PPx)

Applicant Name: Anuncia Medical Inc

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The ReFlow® Guardian™ PPx Catheter Clearance System is an implantable, manually actuated catheter clearance device placed in-line between the ventricular catheter and the valve of a cerebrospinal fluid (CSF) shunt system. Its proposed expanded indication adds physician-prescribed prophylactic flushing of an un-occluded ventricular catheter.



Technology Name

Generic Name: OPM

Trade Name: Mg OSTEOCRETE Protein Matrix

Applicant Name: Bone Solutions Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Mg OSTEOCRETE Protein Matrix is an innovative magnesium-based bone void filler that combines the osteostimulative properties and adhesive strength of magnesium phosphate with the osteoinductive potential of allograft bone fibers. Its injectable or moldable formulation provides a cohesive scaffold designed to support bone regeneration and remodeling



Technology Name

Generic Name: Percutaneous Catheter

Trade Name: Millipede System (Millipede88 Aspiration Catheter and Perfuze Tube Set)

Applicant Name: Perfuze Ltd.

Application Pathway: Alternative

Has the technology already received a Breakthrough Device/QIDP designation or LPAD approval from FDA for the indication relevant to this application? Yes

Brief Description of the Technology:

The Millipede System (Millipede88 Aspiration Catheter and Perfuze Aspiration Tube Set) is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within several cerebral and carotid arteries within 8 hours of symptom onset.