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Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS) for Federal Fiscal Year (FY) 2026

Number of Requests Under Review: 49

Technology Name

Generic Name: Peptide Enhanced Bone Void Filler

Trade Name: PearlMatrix P-15 Peptide Enhanced Bone Graft

Applicant Name: Cerapedics 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:

PearlMatrix P-15 Peptide Enhanced Bone Graft is a composite bone graft material consisting of a synthetic peptide, found naturally occurring in human Type I collagen (P-15), adsorbed onto calcium phosphate particles, which are incorporated into a fibrous collagen matrix putty as an inert carrier.

Note: The information on this tracking form was provided by the applicant at the time of application submission.

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Technology Name

Generic Name: Emily's Care

Trade Name: Emily's Care Nourish Test System (Model 1)

Applicant Name: Lactation Lab 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 Emily's Care Nourish Test System (Model 1) is an FDA Approved Breakthrough Device. It is an analytical system designed to measure the concentration of fat, carbohydrates (lactose), and protein in human milk at point of care using an enzyme-based test strip and a smartphone camera with an associated application.

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Technology Name

Generic Name: Wrapsody Cell-Impermeable Endoprosthesis (CIE)

Trade Name: Merit Wrapsody® Cell Impermeable Endoprosthesis

Applicant Name: Merit 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:

A flexible self-expanding (CIE) to treat venous outflow circuit stenosis or occlusion in patients with hemodialysis fistula or graft. FDA Breakthrough prevents transgraft cellular migration resulting in RCT multicenter 6-month target lesion primary patency (TLPP) (90% vs 63%) compared to percutaneous transluminal angioplasty (PTA) and equal safety.

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Technology Name

Generic Name: fosfomycin

Trade Name: CONTEPO

Applicant Name: Meitheal Pharmaceuticals 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:

CONTEPO™ (Fosfomycin) for injection is a broad spectrum intravenous (IV) antibiotic for the treatment of complicated urinary tract infection including acute pyelonephritis due to difficult to treat Gram-negative and Gram-positive bacteria.

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Technology Name

Generic Name: Drug-eluting percutaneous transluminal coronary angioplasty catheter

Trade Name: AGENT™ Paclitaxel-Coated Balloon Catheter

Applicant Name: Boston Scientific 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 AGENT Paclitaxel-Coated Balloon Catheter is a semi-compliant percutaneous coronary intervention (PCI) catheter; the balloon portion of the device is coated with a TransPax coating. The AGENT Drug Coated Balloon is designed to inhibit restenosis by delivering the drug, paclitaxel, to the diseased coronary arterial tissue.

Technology Name

Generic Name: bentracimab

Applicant Name: SERB Pharmaceuticals (SERB) (previously known in the U.S. as BTG Pharmaceuticals)

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 nondeferrable surgery or invasive procedure and in patients experiencing major bleeding, in whom ticagrelor impairs normal hemostasis.

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Technology Name

Generic Name: aztreonam-avibactam

Trade Name: TBD

Applicant Name: Manufacturer

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:

Aztreonam-avibactam (ATM-AVI) is an investigational intravenous antibiotic treatment for infections caused by Gram-negative bacteria with limited treatment options. It combines aztreonam, a monobactam β-lactam, with avibactam, a potent broad-spectrum β-lactamase inhibitor.

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Technology Name

Generic Name: Vascular Conduit Solution

Trade Name: DuraGraft

Applicant Name: Marizyme, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

DuraGraft is a first-in-class product used during coronary artery bypass grafting surgery (CABG) in adult patients to protect the vascular endothelia of harvested vascular grafts during the ischemic graft storage interval.

Technology Name

Generic Name: zanidatamab-hrii

Applicant Name: Jazz Pharmaceuticals

Application Pathway: Traditional

Brief Description of the Technology:

Zanidatamab is an investigational human epidermal growth factor receptor 2 (HER2)-directed bispecific antibody. The initial target indication for zanidatamab is for the treatment of adults with previously treated, unresectable/metastatic HER2-positive (HER2+) (IHC3+) biliary tract cancer (BTC), as detected by an FDA-approved test.

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Technology Name

Generic Name: Drug Eluting Resorbable Scaffold System

Trade Name: Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

Applicant Name: Abbott Laboratories

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 Esprit BTK Everolimus Eluting Resorbable Scaffold is a temporary scaffold that will resorb over time and is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb threatening ischemia (CLTI).

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Technology Name

Generic Name: tabelecleucel (tab-cel)

Applicant Name: Pierre Fabre Pharmaceuticals, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Tab-cel is a non-genetically modified allogeneic, off-the-shelf, Epstein-Barr Virus (EBV)-specific T-cell immunotherapy under investigation as monotherapy for treatment of adult and pediatric patients 2 years of age and older with EBV positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy.

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Technology Name

Generic Name: Rozanolixizumab-noli

Trade Name: RYSTIGGO

Applicant Name: UCB, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

RYSTIGGO (rozanolixizumab-noli) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

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Technology Name

Generic Name: Sorbent Hemoperfusion Device

Trade Name: DrugSorb-ATR Device

Applicant Name: CytoSorbents, 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 DrugSorb-ATR device is indicated for the removal of ticagrelor to reduce the severity of perioperative bleeding in patients undergoing coronary artery bypass grafting (CABG) within two days of ticagrelor discontinuation.

Technology Name

Generic Name: lisocabtagene maraleucel

Trade Name: BREYANZI®

Applicant Name: Bristol Myers Squibb (BMS)

Application Pathway: Traditional

Brief Description of the Technology:

BREYANZI® (lisocabtagenbe maraleucel) is a CD19-directed, autologous CAR T-cell immunotherapy comprised of individually formulated CD8 and CD4 CAR T-cells, indicated for the treatment of adult patients with R/R CLL/SLL who have received ≥2 prior LOT including a BTKi and a BCL2i - the first CAR T-cell therapy indicated for these patients.

Technology Name

Generic Name: VITEK REVEAL AST System

Trade Name: VITEK REVEAL AST System

Applicant Name: bioMerieux

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 VITEK® REVEAL™ AST System is an in vitro diagnostic automated system for the quantitative antimicrobial susceptibility testing of organisms from positive blood culture. Test results are intended to be used in conjunction with Gram stain, organism identification and other clinical findings to inform antibiotic therapy treatment decisions.

Technology Name

Trade Name: alfapump system

Applicant Name: Sequana Medical NV

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 alfapump® system is an implanted subcutaneous device with rechargeable battery allowing fluid removal from the peritoneal cavity to the urinary bladder where it is then eliminated via urination; provides an alternative to standard treatments for refractory ascites, i.e. lge vol, paracentesis (LVP) with albumin, transjugular intrahepatic shunts

Technology Name

Generic Name: interatrial shunt

Trade Name: Ventura Interatrial Shunt System

Applicant Name: V-Wave, 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 Ventura Interatrial Shunt System includes the Ventura Interatrial Shunt and delivery system. It is indicated to reduce morbidity and mortality in NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy and have a left ventricular ejection fraction of ≤40%.

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Technology Name

Generic Name: Ankle Truss System

Trade Name: 4WEB Medical Ankle Truss System

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 Medical Ankle Truss System (ATS) is for use with a premarket authorized tibiotalocalcaneal (TTC) nail as part of a TTC fusion system to manage ankle bone defects that occur after a failed ankle arthrodesis or arthroplasty.

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Technology Name

Generic Name: TNT

Trade Name: iFuse TORQ TNT™ 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:

The iFuse TORQ TNT Implant System consists of a fully threaded, 3D-printed porous anatomy-specific implant with optional washers along with instruments used to place the implant under either fluoroscopic guidance or with certain navigation systems. The implant has features specific to pelvic anatomy for fracture fixation or sacroiliac joint fusion.

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Technology Name

Generic Name: Sepsis aiMarker

Trade Name: Sepsis aiMarker™

Applicant Name: Biocogniv 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 Sepsis aiMarker is a technology used to aid in identifying patients at risk for having or developing sepsis. The technology analyzes a patient's laboratory results and vitals using a fixed Artificial Intelligence/Machine Learning (AI/ML)-based algorithm to determine a risk score and assign a normal or abnormal category for risk of sepsis.

Technology Name

Generic Name: restor3d TIDAL Fusion Cage

Trade Name: restor3d TIDAL Fusion Cage

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:

The restor3d TIDAL Fusion Cages are additively manufactured porous cages intended to be used as an accessory to an intramedullary nail for internal bone fixation for bone fractures, bone voids, or surgical resections in the hindfoot and tibia.

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Technology Name

Generic Name: obecabtagene autoleucel (obe-cel)

Applicant Name: Autolus Therapeutics plc

Application Pathway: Traditional

Brief Description of the Technology:

Obecabtagene autoleucel (obe-cel) is a novel fast off-rate CD19 autologous chimeric antigen receptor (CAR) T-cell therapy with first-in-class tumor burden-guided dosing designed to improve persistence and reduce immune-mediated toxicity. Obe-cel is under investigation for treatment of adult relapsed/refractory B-cell Acute Lymphoblastic Leukemia.

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Technology Name

Generic Name: Peripheral Retrievable Stent System

Trade Name: Spur Peripheral Retrievable Stent System

Applicant Name: Reflow 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 Spur Peripheral Retrievable Stent System is intended for the treatment of de novo or restenotic lesions of the infrapopliteal arteries to increase luminal diameter. It places a temporary stent within the lesion and is removed during the procedure.

Technology Name

Generic Name: Lungpacer Diaphragm Pacing Therapy System

Trade Name: AeroPace® System

Applicant Name: Lungpacer(R) 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 AeroPace® System is intended for temporary stimulation of the phrenic nerve(s) to increase diaphragmatic strength. It is indicated to improve weaning success, reduce ventilator days, and reduce reintubation in patients 18 years and older on mechanical ventilation ≥96 hours and who have not weaned.

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Technology Name

Generic Name: afamitresgene autoleucel (afami-cel)

Trade Name: TECELRA®

Applicant Name: Adaptimmune

Application Pathway: Traditional

Brief Description of the Technology:

TECELRA is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma (SyS) who have received prior chemotherapy, are HLA-A*02 subtype positive, and whose tumor expresses the MAGE-A4 antigen.

Technology Name

Generic Name: Stent, Carotid

Trade Name: Neuroguard IEP® 3-in-1 Carotid Stent and Post-Dilation Balloon System with Integrated Embolic Protection (Neuroguard IEP System)

Applicant Name: Contego Medical, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

The Neuroguard IEP System combines a carotid stent with an integrated 40 µm embolic protection filter and post-dilation balloon. This system restores and maintains vessel patency while stabilizing plaque. By capturing smaller emboli during critical phases, it reduces the risk of stroke during the procedure and helps prevent future strokes.

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Technology Name

Generic Name: WiSE CRT System

Trade Name: The WiSE CRT System

Applicant Name: EBR Systems, 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 WiSE CRT System is indicated for patients who meet current guidelines for cardiac resynchronization therapy (CRT) with previously acute or chronic failed implants or patients that are high-risk upgrades to a traditional CRT device.

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Technology Name

Generic Name: Fibrinogen (Human)

Trade Name: Fibryga

Applicant Name: Octapharma USA, Inc

Application Pathway: Traditional

Brief Description of the Technology:

FIBRYGA is a human fibrinogen concentrate indicated for: • fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency • treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia (1).:

Technology Name

Trade Name: Minima Stent System

Applicant Name: Renata 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 Minima Stent System is the first and only stent designed, tested, clinically trialed, and FDA approved for treating coarctation of aorta and pulmonary artery stenosis in neonates, infants, and young children > 1.5 kg. Not only can it be implanted that small, but it is also designed to be re-expanded over time up to adult size vessels.

Technology Name

Generic Name: Transdermal GFR system utilizing Relmapirazin

Trade Name: Transdermal GFR System utilizing Lumitrace® (needs FDA confirmation)

Applicant Name: MediBeacon- Manufacturer

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 Transdermal Glomerular Filtration Rate (TGFR) System is a multi-component system: 1) a TGFR reusable sensor, 2) a TGFR sensor adhesive ring, 3) a TGFR monitor, 4) Lumitrace® (relmapirazin), a proprietary fluorescent tracer agent removed from the blood exclusively by the GFR mechanism of the kidney

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Technology Name

Generic Name: Not Applicable (NA)

Trade Name: ShortCut

Applicant Name: Pi-Cardia 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 ShortCut™ is indicated for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk of coronary obstruction

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Technology Name

Generic Name: IntelliSep Test

Trade Name: IntelliSep Test

Applicant Name: Cytovale, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

The IntelliSep Test is a semi-quantitative test that assesses cellular host response via deformability cytometry of leukocyte biophysical properties and is intended for use alongside clinical assessments and laboratory findings to aid in the early detection of sepsis with organ disfunction for adults presenting to the Emergency Department.

Technology Name

Generic Name: acellular tissue engineered vessel-tyod (ATEV)

Trade Name: To be updated post approval

Applicant Name: Humacyte

Application Pathway: Traditional

Brief Description of the Technology:

ATEV is a first-in-class, bioengineered, implantable blood vessel offering a new treatment option for patients. ATEV's anticipated indication is for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein graft is not feasible.

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Technology Name

Generic Name: Not applicable

Trade Name: Nelli Seizure Monitoring System

Applicant Name: Neuro Event Labs

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:

Nelli is a prescription-only device that is designed to be used as an adjunct to seizure monitoring in a hospital inpatient or home setting for adults and children 6 years of age and older. Nelli's software is designed to automate the analysis of audio and video data to identify seizure events with a positive motor component.

Note: The information on this tracking form was provided by the applicant at the time of application submission.

Technology Name

Generic Name: Hospital Continuous Glucose Monitoring System

Trade Name: Dexcom G7 Hospital Continuous Glucose Monitoring System

Applicant Name: Dexcom

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 Dexcom G7 Hospital Continuous Glucose Monitoring System (Dexcom Hospital System) is a real-time CGM device indicated for use by healthcare professionals to monitor and manage glucose levels of patients ages 18 years and older in a hospital environment

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Technology Name

Generic Name: iloprost

Trade Name: AURLUMYN

Applicant Name: SERB Pharmaceuticals (SERB) (previously known in the U.S. as BTG Pharmaceuticals)

Application Pathway: Traditional

Brief Description of the Technology:

AURLUMYN is a prostacyclin mimetic indicated for the treatment of severe frostbite in adults to reduce the risk of digit amputations. AURLUMYN is the first and only drug therapy approved in the U.S. for the treatment of frostbite.

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Technology Name

Generic Name: Aortic Arch Hybrid Prosthesis

Trade Name: AMDS™ Hybrid Prosthesis

Applicant Name: Artivion, 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:

AMDS is comprised of an implantable stent supplied loaded onto a delivery system which is inserted into the transected aorta during a standard hemiarch repair procedure to treat patients with acute DeBakey Type I aortic dissections.

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Technology Name

Trade Name: FFX® Implant

Applicant Name: SC Medica

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:

FFX is a titanium device to be fixed In the facet joint In adult patients. They are intended to be used with bone graft and facet screws to achieve lumbar fusion through immobilization of the lumbar facet joints.

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Technology Name

Generic Name: Intracompartmental Pressure Monitor

Trade Name: MY01 Continuous Compartmental Pressure Monitor

Applicant Name: MY01 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 MY01 Continuous Compartmental Pressure Monitor is a single-use device that measures and displays in real-time muscle compartment pressure as an aid in Compartment Syndrome diagnosis. The companion Mobile App displays identical muscle pressure data together with calculated perfusion pressure using a manually entered diastolic blood pressure.

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Technology Name

Trade Name: TriVerity Test

Applicant Name: Inflammatix, 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 TriVerity test is a blood test that rapidly "reads" the body's immune response to infection using machine learning-derived algorithms. The test informs on the presence of infection and risk of progression to severe illness in adult patients suspected of acute infection or sepsis in the emergency department.

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Technology Name

Generic Name: EUROPA Posterior Cervical Fusion System

Trade Name: EUROPA™ Posterior Cervical Fusion System

Applicant Name: MiRus, LLC, 1755 W Oak Parkway, Suite 100, Marietta, GA 30062

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 EUROPA™ Posterior Cervical Fusion System is a posterior cervical screw system intended to provide structural stability and mechanical support to the cervical spine through posterior cervical fusion. The EUROPA™ Posterior Cervical Fusion System implants are offered in multiple configurations and different sizes to accommodate various needs.

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Technology Name

Generic Name: Selux DPBC and AST System (AST Gen 1.5)

Trade Name: PBC Separator with Selux AST System

Applicant Name: Selux Diagnostics, 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 PBC Separator with Selux AST System is a phenotypic antimicrobial susceptibility testing (AST) system, intended to assist medical professionals in the identification of in vitro susceptibility or resistance to specific antimicrobial agents.

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Technology Name

Generic Name: custom-made anatomically designed cervical interbody fusion device

Trade Name: aprevo®-C cervical interbody fusion device

Applicant Name: Carlsmed, 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 aprevo®-C cervical interbody fusion devices are intended to stabilize intervertebral spaces of the cervical spine (C2-T1) and facilitate fusion. The devices are custom-made to achieve a patient-specific cervical alignment plan and have surfaces that match the irregular topography of each patient's cervical vertebral endplates.

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Technology Name

Generic Name: Treosulfan

Trade Name: Grafapex

Applicant Name: Medexus Pharma, Inc.

Application Pathway: Traditional

Brief Description of the Technology:

Treosulfan is a novel conditioning agent used for allogenic hematopoietic stem cell transplantation. If approved, it will be the only FDA-approved conditioning agent for acute myeloid leukemia and myelodysplastic syndrome. Treosulfan has shown superiority in event-free survival, overall survival, and non-relapse mortality compared to other agents.

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Technology Name

Trade Name: CERAMENT® G

Applicant Name: BONESUPPORT 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:

CERAMENT® G is an implantable bone void filler (device/drug combination product), consisting of calcium sulfate, hydroxyapatite, and gentamicin sulfate. CERAMENT® G elutes 17.5 mg gentamicin/ mL paste. [CERAMENT G IFU, CERAMENT G Value Guide]

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Technology Name

Generic Name: tarlatamab-dlle

Trade Name: IMDELLTRA

Applicant Name: Amgen Inc.

Application Pathway: Traditional

Brief Description of the Technology:

IMDELLTRA is a novel, first-in-class, Bispecific T-cell Engager (BiTE®) molecule that binds the antigen DLL3 expressed on the surface of SCLC cells and CD3 expressed on the surface of T cells causing T-cell activation, release of inflammatory cytokines, and lysis of DLL3-expressing cells for the treatment of 2L+ ES-SCLC.

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Technology Name

Generic Name: Sub-Epidermal Moisture Assessment Technology

Trade Name: Provizio® SEM Scanner

Applicant Name: Bruin Biometrics, 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 Provizio® SEM Scanner is a wireless, hand-held, bedside device with a touch-screen interface. The technology is non-invasive and detects, measures, and monitors sub-epidermal moisture (SEM), persistent focal edema, or localized edema to detect early-stage pressure injuries/ulcers (PI/PUs) and deep tissue pressure injuries (DTPIs).

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Technology Name

Generic Name: Xanomeline and trospium chloride

Trade Name: COBENFY

Applicant Name: Manufacturer

Application Pathway: Traditional

Brief Description of the Technology:

COBENFY is a combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, indicated for the treatment of schizophrenia in adults. It was approved under a New Drug Application.

Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Technology Name

Trade Name: RECELL® Autologous Cell Harvesting Device

Applicant Name: AVITA 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 RECELL® Autologous Cell Harvesting Device (RECELL System) is a stand-alone, single-use, battery-powered medical device that is used to process and apply a skin cell suspension autograft for the treatment of thermal burn wounds and full thickness skin defects. This NTAP application is for the full thickness skin defects indication.

Note: The information on this tracking form was provided by the applicant at the time of application submission.