

Supplemental Online Content

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eTable. Moderate-Risk Therapeutic Devices Cleared Through the FDA's De Novo Pathway Between 2011 and 2019

This supplemental material has been provided by the authors to give readers additional information about their work.

eTable. Moderate-Risk Therapeutic Devices Cleared Through the FDA’s De Novo Pathway Between 2011 and 2019

Device Name	Device Manufacturer	Clearance Date	Therapeutic Area¹	Clinical use¹
Hem-Avert Perianal Stabilizer	Plexus Biomedical Inc.	01/13/2011	Obstetrics/Gynecology	Hemorrhoid prevention pressure wedge
WidexLink In Clear Series Hearing Aids	Widex Hearing Aid Company	03/31/2011	Otolaryngology	Hearing aid, air conduction with wireless technology
Mandometer III ²	AB Mando	03/31/2011	Neurology	Eating disorder conditioning tool
Lipflow Thermal Pulsation System (Formerly Manual Mini System)	Tearscience, Inc.	06/28/2011	Ophthalmology	Eyelid thermal pulsation system
NuCLEUS and NuCLEUS-X BAV Catheter	Numed, Inc.	06/11/2012	Cardiovascular	Balloon aortic valvuloplasty
Virulite Cold Sore Machine	Virulite LLC	10/18/2012	General & Plastic Surgery	Light based treatment for cold sores herpes simplex virus-1
AHIP Internal Trigger Point Wand	National Center For Pelvic Pain Research Devices, Inc.	11/20/2012	Physical Medicine	Massager, therapeutic, to internally massage trigger points in the pelvic floor musculature
Bio-Seal Lung Biopsy Tract System	Angiotech	12/19/2012	Anesthesiology	Absorbable lung biopsy plug
Cabochon System	Cabochon Aesthetics, Inc.	07/12/2013	General & Plastic Surgery	Powered surgical instrument for improvement in the appearance of cellulite
UroLift System	NeoTract, Inc.	09/13/2013	Gastroenterology & Urology	Implantable transprostatic tissue retractor system
eNeura Therapeutics® Cerena Transcranial Magnetic Stimulator	eNeura Therapeutics LLC	12/13/2013	Neurology	Transcranial magnetic stimulator for the treatment of migraine headache
Symphony Device	Sensory Medical, Inc	12/18/2013	Neurology	Vibratory counter-stimulation
AXIOS Stent and Delivery System	Xlumena, Inc	12/18/2013	Gastroenterology & Urology	Pancreatic stent, covered, metallic, removable
Cefaly	STX-Med SPRL	03/11/2014	Neurology	Stimulator, nerve, electrical, transcutaneous, for migraine
XSTAT	RevMedx, Inc.	04/03/2014	General & Plastic Surgery	Non-absorbable, expandable, hemostatic sponge for temporary internal use
DEKA Arm System	DEKA Integrated Solutions Corporation	05/09/2014	Physical Medicine	Upper extremity prosthesis with multiple simultaneous degrees of freedom and controlled via cutaneous electromyography
ReWalk	Argo Medical Technologies, Inc.	06/26/2014	Neurology	Powered exoskeleton

Medtronic DUET External Drainage and Monitoring System	Medtronic Neurosurgery	08/22/2014	Neurology	External cerebrospinal fluid (csf) diversion
inFlow Intraurethral Valve-Pump and Activator	Vesiflo, Inc.	10/14/2014	Gastroenterology & Urology	Urethral insert with pump for bladder drainage
Zap-It!	Ecobrand, Ltd.	11/07/2014	Neurology	Piezo-electric stimulator for relief of mosquito bite itch
Zanza-Click	Tecnimed S.r.l.	11/07/2014	Neurology	Piezo-electric stimulator for relief of mosquito bite itch
Eclipse System	Pelvalon, Inc.	02/12/2015	Gastroenterology & Urology	Dynamic rectal control system
Reza Band® Upper Esophageal Sphincter (UES) Assist Device	Somna Therapeutics, LLC	03/06/2015	Ear Nose Throat	External upper esophageal sphincter (UES) compression device
Prolong	Ergon Medical Ltd.	03/20/2015	Gastroenterology & Urology	Vibrator for climax control of premature ejaculation
Brainport V100 Device	Wicab, Inc	06/18/2015	Ophthalmology	Oral electronic vision aid
Esophageal Cooling Device	Advanced Cooling Therapy, LLC	06/23/2015	Cardiovascular	Esophageal thermal regulation and gastric suctioning device
EarLens™ Contact Hearing Device	EarLens™ Corporation	09/29/2015	Otolaryngology	Tympanic membrane direct contact hearing aid
Sonablate 450	Sonacare Medical, LLC.	10/09/2015	Gastroenterology & Urology	High intensity ultrasound system for prostate tissue ablation
Dignitana AB Dignicap System	Dignitana Ab	12/08/2015	General & Plastic Surgery	Scalp cooling system
Newa™ Skin Therapy System	EndyMed Medical Ltd.	12/18/2015	General & Plastic Surgery	Over-the-counter radiofrequency coagulation device for wrinkle reduction
Cerêve Sleep System	Cerêve, Inc.	05/13/2016	Neurology	Thermal system for insomnia
WallFlex Biliary RX Fully Covered Stent System RMV	Boston Scientific	06/03/2016	Gastroenterology & Urology	Biliary stent system for benign strictures
Modified Trevo ProVue Retriever, Trevo XP ProVue Retriever 4x20mm, Trevo XP ProVue Retriever 3x20mm, Trevo XP ProVue Retriever 6x25mm, Trevo XP ProVue Retriever 4x30mm	Concentric Medical, Inc.	09/02/2016	Neurology	Neurovascular mechanical thrombectomy device for acute ischemic stroke treatment
ACCLARENT AERA™ Eustachian Tube Balloon Dilation System	ACCLARENT, Inc.	09/16/2016	Otolaryngology	Eustachian tube balloon dilation device
Sensor Monitored Alimentary Restriction Therapy (SMART) Device	Scientific Intake	09/26/2016	Gastroenterology & Urology	Oral removable retainer for weight management
AeroForm® Tissue Expander System	AirXpanders, Inc	12/21/2016	General & Plastic Surgery	Carbon dioxide gas controlled tissue expander
Gammacore Non-Invasive Vagus Nerve Stimulator	Electrocore, LLC	04/14/2017	Neurology	Non-invasive vagus nerve stimulator - headache

Oculeve Intranasal Tear Neurostimulator Device	Oculeve, Inc.	04/24/2017	Ophthalmology	Intranasal electrostimulation device
Sentinel Cerebral Protection System	Claret Medical, Inc.	06/01/2017	Cardiovascular	Temporary catheter, embolic protection, transcatheter intracardiac procedures
Embosphere Microspheres	Biosphere Medical S.A.	06/21/2017	Gastroenterology & Urology	Agents, embolic, for treatment of benign prostatic hyperplasia
D2 Dressing ²	Z-Medica, LLC	06/30/2017	General & Plastic Surgery	Temporary, internal use hemostatic
ReSet	Pear Therapeutics, Inc.	09/14/2017	Neurology	Computerized behavioral therapy device for psychiatric disorders
NSS-2 System	Innovative Health Solutions (IHS), Inc.	11/15/2017	Neurology	Percutaneous nerve stimulator for opioid withdrawal
IlluminOss Bone Stabilization System	IllminOss Medical, Inc.	12/19/2017	Orthopedics	Rod, fixation, intramedullary and accessories, in-vivo cured, light-activated
AQUABEAM System	PROCEPT BioRobotics Corporation	12/21/2017	Gastroenterology & Urology	Fluid jet removal system
dermaPACE System	SANUWAVE, Inc.	12/28/2017	General & Plastic Surgery	Extracorporeal shock wave device for treatment of diabetic foot ulcers
SkinPen Precision System	Bellus Medical, LLC.	03/01/2018	General & Plastic Surgery	Powered microneedle device
ThermoNeuroModulation Device, TNM Device	Scion NeuroStim, LLC	03/26/2018	Neurology	Thermal vestibular stimulator for headache
Precision Flow® HVNI	Vapotherm, Inc.	04/10/2018	Anesthesiology	High flow/high velocity humidified oxygen delivery device
Cala ONE	Cala Health, Inc.	04/26/2018	Neurology	External upper limb tremor stimulator
Hemospray® Endoscopic Hemostat	Wilson-Cook Medical, Inc.	05/07/2018	General & Plastic Surgery	Hemostatic device for endoscopic gastrointestinal use
TrueTear Intranasal Tear Neurostimulator	Allergan	05/17/2018	Ophthalmology	Intranasal electrostimulation device for dry eye symptoms
CURVE™ Positive Airway Pressure System	FRESCA Medical	06/05/2018	Anesthesiology	Positive airway pressure system
Natural Cycles	Natural Cycles Nordic AB	08/10/2018	Obstetrics/Gynecology	Device, fertility diagnostic, contraceptive, software application
Brainsway Deep Transcranial Magnetic Stimulation (DTMS) System	Brainways Ltd.	08/17/2018	Neurology	Transcranial magnetic stimulation system for obsessive-compulsive disorder
Bose Hearing Aid	Bose Corporation	10/05/2018	Otolaryngology	Self-fitting air-conduction hearing aid
Innovo	Bio-Medical Research Ltd.	11/06/2018	Gastroenterology & Urology	Cutaneous electrode stimulator for urinary incontinence
SEM Scanner (Model 200)	Bruin Biometrics, LLC	12/20/2018	Gastroenterology & Urology	Pressure ulcer management tool

t:slim X2 insulin pump with interoperable technology	Tandem Diabetes Care, Inc.	02/14/2019	Clinical Chemistry	Alternate controller enabled insulin infusion pump
ClearMate	Thornhill Research, Inc.	03/14/2019	Anesthesiology	Isocapnic ventilation device
Plenity	Gelesis, Inc.	04/12/2019	Gastroenterology & Urology	Ingested, transient, space occupying device for weight management and/or weight loss
PREVENA 125 And PREVENA PLUS 125 Therapy Units	KCI USA, Inc.	04/19/2019	General & Plastic Surgery	Negative pressure wound therapy device for reduction of wound complications
Monarch ETNS System	NeuroSigma, Inc	04/19/2019	Neurology	Transcutaneous nerve stimulator for adhd
Nerivio Migra	Theranica Bioelectronics Ltd	05/20/2019	Neurology	Distal transcutaneous electrical stimulator for treatment of acute migraine
IB-Stim	Innovative Health Solutions (IHS), Inc.	06/07/2019	Neurology	Non-implanted nerve stimulator for pain associated with irritable bowel syndrome (IBS)

Source: FDA De Novo Database

(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm>)

¹ Per FDA-designated product codes

² Decision Summary document not available in FDA De Novo Database