THE GALIEN FOUNDATION

PRODUCT: **Cala Trio™**

COMPANY: Cala Health

THERAPEUTIC AREA & INDICATION:
Neuroscience

ABOUT THE PRODUCT

Cala Health's lead product, Cala Trio, is the first non-invasive targeted therapy that reduces hand tremors for adults living with Essential Tremor. A prescription therapy, it is a wrist-worn device calibrated to treat a patient's unique tremor symptoms. When activated, Cala Trio gently stimulates the nerves in the wrist to disrupt the tremulous activity in the brain, without the need for invasive brain surgery or medication. The easy-to-use and effective Cala Trio can be prescribed through an in-person consultation or telemedicine appointment. Therapy is conveniently delivered to the patient's home, and Cala educates patients based on how they learn.

THE GALIEN FOUNDATION

PRODUCT: **CUSTOM*FLEX*® ARTIFICIAL*IRIS***

COMPANY: Clinical Research Consultants, Inc. and HumanOptics AG

THERAPEUTIC AREA & INDICATION: Ophthalmology

ABOUT THE PRODUCT

The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is the world's first and only FDA-approved treatment for aniridia, an eye disorder with complete or partial absence of the iris (the colored part of the eye around the pupil controlling the amount of light entering the eye) from eye injury, trauma or congenitally in the ~1 in 50,000 to 100,000 babies born annually in the U.S. without an iris in their eyes.

The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is custom made for each eye. Using a photograph, colorized silicone is "painted" onto the device to closely mimic the natural eye's color and pattern. The surgically implanted device restores the eye's appearance and alleviates the debilitating light sensitivity and visual symptoms of aniridia.

THE GALIEN FOUNDATION

PRODUCT: **Edwards SAPIEN 3 Ultra™ Transcatheter Heart Valve System**

COMPANY: Edwards Lifesciences

THERAPEUTIC AREA & INDICATION:
Aortic stenosis

ABOUT THE PRODUCT

The Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System was approved in 2019 for the relief of aortic stenosis in low-risk patients with symptomatic heart disease due to severe native calcific aortic stenosis. Aortic stenosis is a severe heart condition in which the opening of the aortic valve narrows, blocking blood flow from the heart to the rest of the body. The SAPIEN 3 Ultra valve is a less invasive catheter-based therapy, performed on a beating heart. The SAPIEN platform of valves is the most clinically studied transcatheter valve in history. More than 500,000 patients globally have benefited from Edwards TAVR.

THE GALIEN FOUNDATION

PRODUCT: **HeartLogic™ Heart Failure Diagnostic**

COMPANY: Boston Scientific Corporation

THERAPEUTIC AREA & INDICATION:
Cardiovascular

ABOUT THE PRODUCT

HeartLogic™ is the first FDA approved Heart Failure Diagnostic in implantable cardiac therapy devices with remote alert capability. HeartLogic represents a new era of remote monitoring and management of heart failure. It proactively predicts worsening of heart failure and alerts clinicians to changes in patient status. This offers the opportunity to direct limited clinical resources to the patients in most need of medical attention and gives clinicians advanced warning to proactively intervene and adjust treatment, ultimately improving patient outcomes. HeartLogic changes the landscape by shifting heart failure patient care from reactive treatment to proactive management.

THE GALIEN FOUNDATION

PRODUCT: **iStent *inject*® W**

COMPANY: Glaukos Corporation

THERAPEUTIC AREA & INDICATION:
Ophthalmology/open-angle glaucoma

ABOUT THE PRODUCT

iStent *inject* W from Glaukos Corporation is a Micro-Invasive Glaucoma Surgery (MIGS) device designed to treat glaucoma, one of the world's leading causes of blindness. This groundbreaking innovation is one of the smallest medical devices implanted in the human body, yet its impact is tremendous. iStent *inject* W is comprised of an injector preloaded with two tiny stents, each measuring 360µm tall x 360µm wide. Each stent is implanted through the eye's trabecular meshwork (primary site of resistance in glaucomatous eyes), creating a bypass from the front part of the eye to the distal outflow system, thereby reducing intraocular pressure.

THE GALIEN FOUNDATION

PRODUCT: **Magtrace® and Sentimag® Magnetic Localization System**

COMPANY: Endomag

THERAPEUTIC AREA & INDICATION:
Oncology

ABOUT THE PRODUCT

Magtrace® and the Sentimag® localization system help any breast cancer patient or any hospital to access the highest standard in breast cancer staging. For patients who have identified a tumor, it is important for their surgeons to understand whether cancer has spread to other parts of the body by checking lymph nodes near the armpit to determine the 'stage' of the disease. The Magtrace® lymphatic tracer is used for this detection and subsequent removal. The Sentimag® system detects Magtrace® signal in the lymph nodes and enables surgeons to be precise in their surgical removal, sparing patients from complications such as lymphedema.

THE GALIEN FOUNDATION

PRODUCT:
PK Papyrus Covered Coronary Stent System

COMPANY: BIOTRONIK

THERAPEUTIC AREA & INDICATION:
Coronary artery perforations

ABOUT THE PRODUCT

Built on BIOTRONIK's ultrathin stent platform, PK Papyrus is the first FDA approved device for the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter. The covered stent is available in 17 sizes, expanding treatment options and helping avoid the need for emergency coronary artery bypass grafting. PK Papyrus is the only 5 French compatible covered coronary stent available in the United States.

THE GALIEN FOUNDATION

PRODUCT: **Digihaler® Platform**

COMPANY: Teva Pharmaceutical Industries

THERAPEUTIC AREA & INDICATION:
Pulmonary respiratory disease

ABOUT THE PRODUCT

The Digihaler® system is a family of digital inhalers with a companion mobile app. Data from the app is securely transferred and stored in a cloud-based digital health platform, and is also accessible in a healthcare professional dashboard. Learn more at Digihaler.com.

THE GALIEN FOUNDATION

PRODUCT: **reSET® and reSET-O®**

COMPANY: Pear Therapeutics

THERAPEUTIC AREA & INDICATION:
Substance use disorder

ABOUT THE PRODUCT

Pear Therapeutics has created a new landscape for treating disease areas with significant unmet needs and established an entirely new class of therapeutics, Prescription Digital Therapeutics (PDTs). Our lead products, reSET and reSET-O, were the first pieces of software authorized by FDA to treat disease. With an estimated 20.3 million Americans suffering, substance use disorder is a public health problem. With FDA market authorizations of both reSET and reSET-O, a new treatment paradigm for substance use disorder and opioid use disorder has evolved in conjunction with advances in medical technology. For more information and important safety information, visit https://www.resetforrecovery.com/.

THE GALIEN FOUNDATION

PRODUCT: **Sentinel™ Cerebral Protection System**

COMPANY: Boston Scientific Corporation

THERAPEUTIC AREA & INDICATION:
Endovascular disease debris repair

ABOUT THE PRODUCT

The SENTINEL™ Cerebral Protection System (CPS) is the first and only device in the US to offer protection from the risk of stroke during TAVR. SENTINEL CPS is an easy-to-use, minimally-invasive, medical device, placed at the beginning of the TAVR procedure. In the SENTINEL IDE, 99% of patients treated with the SENTINEL CPS captured and removed emboli, and the trial demonstrated a significant, 63% reduction in stroke within 72 hours of the TAVR procedure with SENTINEL CPS use. To date, more than 50,000 patients have been protected globally using SENTINEL CPS.

THE GALIEN FOUNDATION

PRODUCT: **The GentleWave® System**

COMPANY: Sonendo®

THERAPEUTIC AREA & INDICATION:
Root canal treatment

ABOUT THE PRODUCT

Tooth decay (i.e. cavities and root canal infections) is the most prevalent chronic disease in the world. However, the drills, burs, and files that are being used to treat tooth decay today, do not adequately clean and disinfect teeth which results in high failure rates. The Sonendo GentleWave® System offers a new and innovative way to clean and disinfect teeth. Studies have shown that the GentleWave System, initially indicated for root canal therapy, can reduce failure rates from about 20-30% to below 3%. More than 450,000 GentleWave procedures have been completed since launch.

THE GALIEN FOUNDATION

PRODUCT: **Venovo™ Venous Stent System**

COMPANY: Becton, Dickinson and Company

THERAPEUTIC AREA & INDICATION:
Iliofemoral venous occlusive circulation disease

ABOUT THE PRODUCT

The Venovo TM Venous Stent System is indicated for the treatment of symptomatic iliofemoral venous outflow obstruction. It is a flexible nitinol stent specifically designed to reopen blocked iliac and femoral veins in order to maintain adequate blood flow. The venous stent is designed with a balance of radial strength, compression resistance, and flexibility needed for the treatment of symptomatic post-thrombotic and non-thrombotic iliofemoral lesions, without compromising on delivery accuracy. Additionally, the broad stent sizing ranging from 10 to 20 mm stent diameters and 40 to 160 mm stent lengths allows clinicians to treat large diameter veins and long lesion lengths.

THE GALIEN FOUNDATION

PRODUCT: **Zephyr Endobronchial Valve System®**

COMPANY: Pulmonx Corporation

THERAPEUTIC AREA & INDICATION:
Emphysema

ABOUT THE PRODUCT

The Zephyr Endobronchial Valve is clinically-proven to help emphysema patients breathe easier, do more, and enjoy life. The Zephyr Valve is the first endobronchial valve to receive approval from the FDA for patients with either heterogeneous or homogeneous emphysema. Our patient selection tools, StratX Lung Analysis Platform and Chartis Pulmonary Assessment System, enable physicians to successfully predict outcomes and provide optimal treatment for each individual patient. Zephyr Valve patients (over 20,000 patients treated globally) report significant improvements in breathing and often within weeks see an improvement in quality of life and the ability to do everyday tasks again with ease.

THE GALIEN FOUNDATION

PRODUCT: **PureWick Female External Catheter / PureWick Urine Collection System**

COMPANY: Becton, Dickinson and Company

THERAPEUTIC AREA & INDICATION:
For non-invasive urine output management in female patients

ABOUT THE PRODUCT

The Purewick™ System is an innovative system, intended for non-invasive urine output management in female patients. The system works outside the body to draw urine away, helping to keep skin dry. The PureWick™ System, comprised of the PureWick™ Urine Collection System and the PureWick™ Female External Catheter, is designed to work outside the body to draw urine into a sealed collection canister, helping to keep skin dry and control odor. Used in over 2,000 U.S. hospitals, the PureWick™ Female External Catheter is a simple and non-invasive way to manage your urinary incontinence at home.

THE GALIEN FOUNDATION

PRODUCT: **AcrySof® IQ PanOptix® Trifocal Intraocular Lens (IOL)**

COMPANY: Alcon Inc.

THERAPEUTIC AREA & INDICATION:
For the visual correction of aphakia in adults

ABOUT THE PRODUCT

THE GALIEN FOUNDATION

PRODUCT: **Allergan Aesthetics**

COMPANY: JUVÉDERM VOLUMA XC

THERAPEUTIC AREA & INDICATION:
To correct skin age-related volume loss

ABOUT THE PRODUCT

JUVÉDERM® VOLUMA® XC was the first injectable gel dermal filler to receive U.S. FDA approval for augmentation of the chin region.[1]

Due to its unique gel properties and product profile, it is designed to benefit areas of the face requiring more volume, such as the chin, and can help provide a more defined chin.[2]

Visit Juvederm.com or talk to your doctor for more information. To report a side effect with any JUVÉDERM® product, please call Allergan at 1-800-433-8871.

References:

1. JUVÉDERM® VOLUMA® XC FDA Approval for Chin, June 2020.
2. JUVÉDERM® VOLUMA® XC Patient Labeling for Chin, 2020.

THE GALIEN FOUNDATION

PRODUCT: **Barostim™**

COMPANY: CVRx, Inc.

THERAPEUTIC AREA & INDICATION:
Treatment of Heart Failure with Reduced Ejection Fraction (HFrEF)

ABOUT THE PRODUCT

CVRx's Barostim Baroflex Activation Therapy is the first medical technology approved by the FDA that uses neuromodulation - the power of the brain and nervous system - to improve the symptoms of patients with systolic heart failure (HFrEF). Barostim is delivered by the Barostim NEO Generator™, an implantable device that uses CVRx-patented technology to send electrical pulses to baroreceptors located in the wall of the carotid artery. Baroreceptors trigger the body's baro-reflex which in turn triggers an autonomic response to the heart. The therapy is designed to restore balance to the autonomic nervous system and thereby reduce the symptoms of HF. Barostim NEO received the FDA Breakthrough Device Designation and is FDA-approved for use in HF patients in the US. It has also received the CE Mark for HF and resistant hypertension in the European Economic Area. To learn more about Barostim, watch this video: https://bit.ly/3xgvLZm

THE GALIEN FOUNDATION

BEST MEDICAL TECHNOLOGY
PRIX GALIEN USA
NOMINEE 2021

PRODUCT: **VersaCross Transseptal Platform**

COMPANY: Baylis Medical

THERAPEUTIC AREA & INDICATION:
Creates interatrial communication in the heart

ABOUT THE PRODUCT

The VersaCross® RF Transseptal Solution is the world's first RF wire-based solution to left heart access. The VersaCross® Solution aims to make transseptal access more efficient and effortless by eliminating device exchanges and streamlining delivery of therapy sheaths. This solution includes a novel 3-in-1 RF wire that acts as a starter wire, RF puncture device and supportive exchange rail. The versatile wire features Baylis' proprietary RF puncture technology; shown to be more efficient and reduce risk of serious complications.[1]

The VersaCross® Solution is used in life-changing procedures, including cardiac ablation, left atrial appendage closure, and mitral valve repair.

1. Hsu et al. J Am Heart Assoc. 2013