S.T. GENESIS™

S.T. Genesis™ is an FDA 510(K) Cleared Class 2 Medical Device Chart

FDA Indications for Use	Percutaneous Nerve Field Stimulatory (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by transillumination.
FDA Product Classification Database	(Source) https://www.accessdata.fda.gov/
Product Code	PZR (newly granted FDA product Code effective 2/5/2018)
Device	Percutaneous Nerve Stimulator For Opioid Withdrawal
Regulation Description	Percutaneous nerve stimulator for substance use disorders
Definition	Stimulate nerve branches to aid in the reduction of symptoms associated with substance use disorders
Physical State	A signal generator connected to percutaneous electrodes
Technical Method	Electrical stimulation of nerve branches using percutaneous electrodes
Target Area	Cranial and occipital nerve branches
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	PZR
Premarket Review	Neuromodulation and Physical Medicine Devices (DHT5B)
Submission Type	510(k)
Regulation Number	882.5896
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt	No
Summary Malfunction Reporting	Ineligible
Implanted Device	No
Life-Sustain/Support Device	No
Third Party Review	Not Third Party Eligible

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