NEUROMetrix®

May 28, 2020

To Whom it May Concern

Subject: Quell® eligibility for FSA, HSA and HRA

Quell, manufactured by NeuroMetrix, Inc. (Woburn, MA, USA), is an over-the-counter transcutaneous electrical nerve stimulation (TENS) device. It has FDA 510(k) Clearance (K152954) under 21CFR882.5890 with product classification code NUH ("Stimulator, Nerve, Transcutaneous, Over-The-Counter). Product regulatory details from the FDA website are provided below.

Device Classification Name	Stimulator, Nerve, Transcutaneous, Over-The-Counter
510(K) Number	K152954
Device Name	Quell
Applicant	NEUROMETRIX, INC. 1000 WINTER STREET Waltham, MA 02451
Applicant Contact	Rainer Maas
Correspondent	NEUROMETRIX, INC. 1000 WINTER STREET Waltham, MA 02451
Correspondent Contact	Rainer Maas
Regulation Number	882.5890
Classification Product Code	NUH
Date Received	10/07/2015
Decision Date	01/05/2016
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Neurology
510k Review Panel	Neurology
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

The Quell device and Quell electrodes are eligible over-the-counter products for flexible spending accounts (FSA), health savings accounts (HSA) and health reimbursement arrangements (HRA).