FDA

Class 2 Device Recall VNS Therapy AspireSR Generator

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Class 2 Device Recall VNS Therapy AspireSR Generator

See Related Information[22]

Date Initiated by Firm	December 18, 2015
Date Posted	January 15, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0659-2016
Recall Event ID	72896[23]
PMA Number	P970003[24]
Product Classification	Stimulator, autonomic nerve, implanted for epilepsy[25] - **Product Code** LYJ[26]
Product	VNS Therapy AspireSR Generator Model 106. Indicated for use as an adjunctive therapy in reducing the frequency of seizures.
Code Information	All VNS Therapy AspireSR (Model 106) Generators; Device Identifier - (01)05425025750061
Recalling Firm/ Manufacturer	Cyberonics, Inc 100 Cyberonics Blvd Houston TX 77058-2069
For Additional Information Contact	Clinical Technical Support 866-882-8804
Manufacturer Reason for Recall	Recall being initiated in response to three reports of "Burst Watchdog Timeout" events occurring with the Model 106 AspireSR Generator, resulting in a device reset condition where stimulation output is disabled.
FDA Determined Cause [2]	Device Design
Action	The firm notified consignees of the issue via letter on 12/18/15. The letter identified the affected device, the issue involved, and actions to be taken. Physicians are to contact Clinical Technical Support at 866-882-8804 to report if a patient's generator has been disabled due to the issue identified. Users are to complete and return the effectiveness card as soon as possible. If further information is needed, customers can contact Clinical Technical Support at 866-882-8804 or via e-mail at cservices@livanova.com.
Quantity in Commerce	4,935 units
Distribution	Worldwide Distribution -- United States, Austria, Belgium, Croatia, Czech Republic, Finland, France, Germany, Iceland, Italy, Netherlands, Norway, Poland, Slovakia, Spain, Sweden, Switzerland, United Kingdom, Cyprus, Israel, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, and United Arab Emirates.
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].