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**Class 2 Device Recall Cyberonics VNS Therapy AspireSR Generator Model 106**



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[CFR Title<sup>21</sup>](#) | [Radiation-Emitting Products<sup>17</sup>](#) | [X-Ray Assembler<sup>18</sup>](#) | [Medsun Reports<sup>19</sup>](#) | [CLIA<sup>20</sup>](#) | [TPLC<sup>21</sup>](#) | [Inspections<sup>22</sup>](#)

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**Class 2 Recall  
Cyberonics VNS Therapy AspireSR  
Generator Model 106**



|   |   |
|---|---|
| <b>Date Posted</b>                            | November 17, 2015   |
| <b>Recall Status<sup>1</sup></b>              | Open  |
| <b>Recall Number</b>                          | Z-0280-2016   |
| <b>Recall Event ID</b>                        | <a href="#">72385<sup>24</sup></a>  |
| <b>Product Classification</b>                 | <a href="#">Stimulator, Autonomic Nerve, Implanted For Epilepsy<sup>25</sup></a> - <a href="#">Product Code LYJ<sup>26</sup></a>  |
| <b>Product</b>                                | Cyberonics Vagus Nerve Stimulator (VNS) Therapy AspireSR Generator, Model 106   |
| <b>Code Information</b>                       | Serial Numbers: 37719, 37899, 38123, 38414, 38428, 39385, 39531, 39607, 39801, 39821, 40037, 40048, 40249, 40251, 40271, 40354, 40428, 40488, 40526, 40603, 40751, 41000, 41109, 41152, 41805, 42022, 42780   |
| <b>Recalling Firm/<br/>Manufacturer</b>       | Cyberonics, Inc<br>100 Cyberonics Blvd<br>Houston, Texas 77058-2069   |
| <b>For Additional<br/>Information Contact</b> | Clinical Technical Support<br>866-882-8804  |
| <b>Manufacturer Reason<br/>for Recall</b>     | Certain Model 106 Pulse Generators demonstrate delays in sensing during use of the 'Verify Heartbeat Detection' feature and exhibit potential for decreased battery longevity.  |
| <b>Action</b>                                 | Cyberonics sent written recall notifications beginning October 14, 2015, to all affected customers. The letter identified the product the problem and the action to be taken by the customer. The notice also directs customers to contact Cyberonics to schedule additional on-site troubleshooting. The on-site troubleshooting proposed by Cyberonics will utilize a feature included within the Model 250 Version 9.0 Programming Software as an alternate method of verifying heart rate and determining that the appropriate heart beat sensitivity setting is programmed. The Version 9.0 software displays an instantaneous heart rate when the user selects the 'Refresh' feature. This heart rate is measured directly by the generator and displayed on the programmer. For further questions, please call (866) 882-8804. |
| <b>Quantity in Commerce</b>                   | 27 units  |
| <b>Distribution</b>                           | US Distribution to the states of : OR, NY, GA, PA, CA, NC, KS, FL, KY, MI, TX, IL, OH, IN, UT, CO and WV.   |
| <b>Total Product Life Cycle</b>               | <a href="#">TPLC Device Report<sup>27</sup></a>   |

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>28</sup>](#)

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