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**Class 2 Device Recall VNS Therapy Programming System**



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**Class 2 Device Recall VNS Therapy Programming System**



**Date Initiated by Firm** January 24, 2018

**Create Date** July 28, 2018

**Recall Status**<sup>1</sup> Open<sup>3</sup>, Classified

**Recall Number** Z-2572-2018

**Recall Event ID** 80424<sup>23</sup>

**PMA Number** P970003<sup>24</sup>

**Product Classification** Stimulator, autonomic nerve, implanted for epilepsy<sup>25</sup> - **Product Code** LYJ<sup>26</sup>

**Product** VNS Therapy Programming System, Rx Only, Model 3000, v1.0.2.2

**Code Information** Part Number 10-0011-0500; Serial Number (UDI Number): FMT77F2 (01054250257503991117091821FMT77F29910 0011 0500), FKR57F2 (01054250257503991117091821FKR57F29910 0011 0500), FCR77F2 (01054250257503991117091821FCR77F29910 0011 0500), CJR77F2 (01054250257503991117091821CJR77F29910 0011 0500), BNT77F2 (01054250257503991117091821BNT77F29910 0011 0500), BNS77F2 (01054250257503991117091821BNS77F29910 0011 0500), 7XR77F2 (010542502575039911170918217XR77F29910 0011 0500), 7XP57F2 (010542502575039911170918217XP57F29910 0011 0500), 79R77F2 (0105425025750399111709182179R77F29910 0011 0500), 90S77F2 (0105425025750399111709182190S77F29910 0011 0500), 97Q57F2 (0105425025750399111709182197Q57F29910 0011 0500), 6NT77F2 (010542502575039911170918216NT77F29910 0011 0500), 9GP57F2 (010542502575039911170918219GP57F29910 0011 0500), 6KX57F2 (010542502575039911170918216KX57F29910 0011 0500), B7Q57F2 (01054250257503991117091821B7Q57F29910 0011 0500), 57P57F2 (0105425025750399111709182157P57F29910 0011 0500), 55T77F2 (0105425025750399111709182155T77F29910 0011 0500), J6R57F2 (01054250257503991117091821J6R57F29910 0011 0500), HWR77F2 (01054250257503991117091821HWR77F29910 0011 0500), 1G7G1F2 (010542502575039911170918211G7G1F29910 0011 0500), 1JR57F2 (010542502575039911170918211JR57F29910 0011 0500), 9XP57F2 (010542502575039911170919219XP57F29910 0011 0500), 4LR77F2 (010542502575039911170919214LR77F29910 0011 0500), 4GT77F2 (010542502575039911170919214GT77F29910 0011 0500), 4GR57F2 (010542502575039911170919214GR57F29910 0011 0500), 2DT77F2 (010542502575039911170919212DT77F29910 0011 0500), G2S77F2 (01054250257503991117092021G2S77F29910 0011 0500), FVQ77F2 (01054250257503991117092021FVQ77F29910 0011 0500), G5T77F2 (01054250257503991117092021G5T77F29910 0011 0500), FDQ57F2 (01054250257503991117092021FDQ57F29910 0011 0500), F5R57F2 (01054250257503991117092021F5R57F29910 0011 0500), F2R57F2 (01054250257503991117092021F2R57F29910 0011 0500), F1Q57F2 (01054250257503991117092021F1Q57F29910 0011 0500), GHS77F2 (01054250257503991117092021GHS77F29910 0011 0500), DVR77F2 (01054250257503991117092021DVR77F29910 0011 0500), DNP57F2 (01054250257503991117092021DNP57F29910 0011 0500), DMYB7F2

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Recalling Firm/

LivaNova USA Inc

<b>Manufacturer</b>	100 Cyberonics Blvd Houston TX 77058-2069
<b>For Additional Information Contact</b>	281-228-7200
<b>Manufacturer Reason for Recall</b>	Unintended warning message displayed on generators programmed with a Model 3000 v.1.0.2.2 programmer.
<b>FDA Determined Cause <sup>2</sup></b>	Software design (manufacturing process)
<b>Action</b>	Consignees were notified on about 01/24/2018 via URGENT: MEDICAL DEVICE CORRECTION letter. Instructions for physicians with new devices (interrogated for the first time) include to 1) apply the changes and proceed with programming as usual. The warning message requires a mandatory action to Apply Changes. After applying changes, therapy will automatically be programmed to 0 mA. The device may be immediately programmed back on to re-enable therapy. 2) To complete and return the attached Customer Response Form (by fax to (281) 853-1248 or by email to M3000FieldAction@livanova.com. Instructions to physicians with devices that have been implanted (previously interrogated) include 1) Restore the normal and magnet mode stimulation parameters from the Summary screen immediately after the warning message screen. If desired, additional programming changes may be made. 2) For AutoStim (M106 only), detection must be re-enabled first, prior to re-enabling AutoStim therapy. The previous AutoStim parameters are not retained and must be reentered manually. If needed, the previous parameters may be found by ending the session and viewing the Session Report for the generator. 3) Please complete and return the attached Customer Response Form by fax to (281) 853-1248 or by email to M3000FieldAction@livanova.com. Additionally customers were instructed to ensure that this notice is communicated to all relevant personnel within the organization. For questions regarding the information in the letter, please contact Clinical Technical Support at (866) 882-8804 (Monday to Friday, 8 AM to 5 PM CST) or e-mail at cservices@livanova.com.
<b>Quantity in Commerce</b>	243 devices total
<b>Distribution</b>	Distributed domestically to AZ, CA, GA, IA, IL, IN, MO, MT, NC, NY, PA, SD, TN, TX, WA, WI.
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>27</sup>

<sup>1</sup> 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](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

<sup>3</sup> The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

**PMA Database** [PMAs with Product Code = LYJ and Original Applicant = LivaNova USA, Inc.](#)<sup>29</sup>

#### Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
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