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Class 2 Device Recall eCare Coordinator

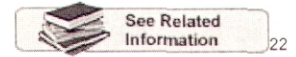


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Class 2 Device Recall eCare Coordinator



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|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date Initiated by Firm | March 02, 2017 |
| Create Date | April 04, 2017 |
| Recall Status ¹ | Open ³ , Classified |
| Recall Number | Z-1708-2017 |
| Recall Event ID | 76660 ²³ |
| 510(K)Number | K141706 ²⁴ |
| Product Classification | Transmitters and receivers, physiological signal, radiofrequency ²⁵ - Product Code DRG ²⁶ |
| Product | <i>eCare Coordinator</i> |

Product Usage: is software intended for use in data aggregation, patient interaction facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The software is intended to provide patient information from the patient location through networking technology to a remote care team. eCare Coordinator does not send any real time alarms and is not intended to provide automated treatment decisions. This software is an informational tool only and is not to be used as a substitute for professional judgment of healthcare providers in diagnosing and treating patients.

Code Information 453564506091 , *eCareCoordinator*.

Recalling Firm/Manufacturer Philips Visicu
217 E Redwood St Ste 1900
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Manufacturer Reason for Recall *eCareCoordinator (eCC) is intended for use in data aggregation, patient interaction facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The software is intended to provide patient information from the patient location through networking technology to a remote care team. A software defect was discovered in the Philips eCareCoordinator (eCC) Clinical User Interface that can at times cause missing or redundant data to be saved without notification to the user.*

FDA Determined Cause² Software Manufacturing/Software Deployment

Action Field Safety Notice (FSN) will be sent to all customers using eCareCoordinator all Versions. The FSN describes the problem and circumstances in which the design defects occurs and the action planned by Philips to correct the problem. The FSN will also detail the functionality change in detail. A software correction will be made and released by the vendor. Customers will have this correction applied to their current version when made available by Vendor in order to fix this correction.

Quantity in Commerce 26

Distribution Worldwide Distribution-US Nationwide

