See Related Information 22

# Class 2 Device Recall Monaco RTP System

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| **Date Initiated by Firm** | September 14, 2021 |
| **Create Date** | September 24, 2021 |
| **Recall Status[1]** | Open[3], Classified |
| **Recall Number** | Z-2563-2021 |
| **Recall Event ID** | 88676[23] |
| **510(K)Number** | K183037[24] K190178[25] |
| **Product Classification** | System, planning, radiation therapy treatment[26] - **Product Code** MUJ[27] |
| **Product** | Elekta Monaco - Product Usage: used to make treatment plans for patients with prescriptions for external beam radiation therapy. |
| **Code Information** | Software Builds: 5.40.00, 5.40.01, 5.40.02, 5.51.10; UDI GTIN: (01)00858164002190(10) 5.40.00, (01)00858164002190(10) 5.40.01, (01)00858164002190(10) 5.40.02, (01)00858164002268(10) 5.51.10 |
| **Recalling Firm/ Manufacturer** | Elekta Inc<br>1450 Beale St Ste 205<br>Saint Charles MO 63303 |
| **For Additional Information Contact** | 314-993-0003 |
| **Manufacturer Reason for Recall** | Contour changes can be saved on an unintended image set. In addition, these contour edits do not cause the dose to be frozen on the plans associated with that image set. |
| **FDA Determined Cause [2]** | Software design |
| **Action** | A Recall notification letter titled, "URGENT IMPORTANT FIELD SAFETY NOTIFICATION" was sent to consignees on 09/14/2021 via email. The letter instructs the consignee of the following:<br><br>"When using Monaco¿ in offline mode, ensure that the active image set is selected in the workspace control when using the Auto Margin tool."<br><br>The consignee is to post the notice in a place that is accessible to all users until the action is |

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| | closed. Furthermore, the consignee is to advise the appropriate personnel, working with this product, on the content of the letter. The firm is requesting that the consignee submit an acknowledgement form as well via the Elekta Care" Community or complete the form and return it to Elekta immediately upon receipt, but no later than within 30 days. |
| **Quantity in Commerce** | 214 units |
| **Distribution** | Worldwide distribution - US Nationwide distribution in the states of PA, MI, WI, NY, TN, NJ, IA, TX and the countries of United Kingdom, Turkey, Switzerland, Sweden, Spain, Netherlands, Korea, Thailand, Japan, Italy, Hong Kong, Germany, France, Denmark, China, Canada, Belgium, Bahrain, Australia. |
| **Total Product Life Cycle** | TPLC Device Report[28] |

[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[29].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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

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| **510(K) Database** | 510(K)s with Product Code = MUJ and Original Applicant = Elekta, Inc[30]<br>510(K)s with Product Code = MUJ and Original Applicant = Elekta, Inc.[31] |

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=88676
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26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MUJ
27. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MUJ
28. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=MUJ
29. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
30. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=MUJ&knumber=&applicant=Elekta%2C%20Inc
31. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=MUJ&knumber=&applicant=Elekta%2C%20Inc%2E

Page Last Updated: 10/13/2021

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
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