Class 2 Device Recall EPTRACER

See Related Information[22]

Date Initiated by Firm	April 25, 2022
Create Date	June 23, 2022
Recall Status[1]	Open[3], Classified
Recall Number	Z-1283-2022
Recall Event ID	90154[23]
510(K)Number	K183266[24]
Product Classification	Computer, diagnostic, programmable[25] - **Product Code** DQK[26]
Product	CardioTek EP-TRACER Software V2.x.
Code Information	EP-TRACER 38 UDI/DI: 04260441455418; Serial Numbers: 2019-1-01, 2019-1-02, 2019-1-03, 2019-1-04, 2019-1-05, 2019-1-06, 2019-2-01, 2019-2-02, 2019-2-03, 2019-2-04, 2019-2-05, 2019-3-01, 2019-3-02, 2019-3-03, 2019-3-04, 2019-3-05, 2019-3-06, 2019-3-07, 2019-3-08, 2019-3-09, 2019-3-10, 2019-4-01, 2019-4-02, 2019-4-03, 2019-4-04, 2019-4-05, 2019-4-06, 2019-4-07, 2019-4-08, 2019-4-09, 2019-4-10, 2019-5-01, 2019-5-02, 2019-5-03, 2019-5-04, 2019-5-05, 2020-1-01, 2020-1-02, 2020-1-03, 2020-1-04, 2020-1-05, 2020-1-06, 2020-1-07, 2020-1-08, 2020-1-09, 2020-1-10, 2020-1-11, 2020-1-12, 2020-1-13, 2020-1-14, 2020-1-15, 2020-2-01, 2020-2-02, 2020-2-03, 2020-2-04, 2020-2-05, 2020-2-06, 2020-2-07, 2020-2-08, 2020-2-09, 2020-2-10, 2020-2-11, 2020-2-13, 2020-2-14, 2020-2-15, 2020-4-01, 2020-4-02, 2020-4-03, 2020-4-04, 2021-1-01, 2021-1-02, 2021-1-03, 2021-1-04, 2021-1-05, 2021-1-06, 2021-1-07, 2021-1-08, 2021-2-01, 2021-2-02, 2021-2-03, 2021-2-04, 2021-2-06, 2021-2-07, 2021-2-08, 2021-2-09, 2021-2-10, 2021-2-11, 2021-2-12, 2021-2-13, 2021-2-14, 2021-2-15, 2021-3-01, 2021-3-02, 2021-3-03, 2021-3-04, 2021-3-05, 2021-3-06, 2021-3-07, 2021-3-08, 2021-3-09, 2021-3-10, 2021-3-11, 2021-3-12, 2021-3-13, 2021-3-14, 2021-3-15, 2021-5-01, 2021-5-02, 2021-5-03, 2021-5-04, 2021-5-05, 2021-5-06, 2022-1-01, 2022-1-03, 2022-1-04, 2022-1-05, 2022-1-06; EP-TRACER 102 UDI/DI: 04260441455234; Serial Numbers: 2019-1-11, 2019-2-11, 2019-2-12, 2019-2-13, 2019-2-14, 2019-2-15, 2019-2-16, 2019-4-21, 2019-4-22, 2019-4-23, 2019-4-24, 2019-4-25, 2019-4-26, 2019-4-27, 2020-1-26, 2020-1-27, 2020-1-28, 2020-1-29, 2020-1-30, 2020-2-26, 2020-2-27, 2020-2-28, 2020-2-29, 2020-2-30, 2021-1-13, 2021-1-14, 2021-2-27, 2022-1-26, 2022-1-27
Recalling Firm/ Manufacturer	CardioTek BV Amerikalaan 70 Maastricht-Airport Netherlands
For Additional Information Contact	490-71312774559

Manufacturer Reason for Recall	Device did not pass electrical safety testing for adequate insulation.
FDA Determined Cause [2]	Under Investigation by firm
Action	The firm issued a recall notification to consignees on 04/25/2022 via email. On 05/24/2022 the firm sent an updated field safety notice. The consignee can continue to use the device. The firm will contact the customer to schedule an appointment for the rework. The consignee is to pass on the letter to those that need to be made aware of the notice.
Quantity in Commerce	146 units
Distribution	Worldwide distribution - US Nationwide distribution in the states of CA, NY, NC and the countries of South Korea, Mexico, Kazakhstan, Netherlands, Spain, Germany, Finland, Poland, Israel, Turkey, Chile, Ecuador, Austria, Croatia, Sweden, United Kingdom, Colombia, Italy, Portugal, Canada, Saudi Arabia, Belgium, Slovenia, Brazil, Hungary, Malaysia, Uzbekistan.
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].

[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.

510(K) Database	510(K)s with Product Code = DQK and Original Applicant = Schwarzer CardioTek GmbH[29]

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27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DQK
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DQK&knumber=&applicant=Schwarzer%20CardioTek%20GmbH

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