



[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

Premarket Approval (PMA)



[510\(k\)](#)⁶ [DeNovo](#)⁸ [Registration](#) [Adverse](#) [Recalls](#)¹¹ [PMA](#)¹² [HDE](#)¹³ [Classification](#)¹⁴ [Standards](#)¹⁵
[& Listing](#)⁹ [Events](#)¹⁰
[CFR Title](#) [Radiation-Emitting](#) [X-Ray](#) [Medsun](#) [CLIA](#)²⁰ [TPLC](#)²¹
[21](#)¹⁶ [Products](#)¹⁷ [Assembler](#)¹⁸ [Reports](#)¹⁹

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Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the [original PMA](#)²³ record for more information.

Device	DEXCOM G5 MOBILE CONTINUOUS GLUCOSE MONITORING SYSTEM
Generic Name	Sensor, glucose, invasive
	DEXCOM, INC.
Applicant	6340 SEQUENCE DR SAN DIEGO, CA 92121
PMA Number	P120005
Supplement Number	S049
Date Received	06/21/2016
Decision Date	09/16/2016
Product Code	MDS ²⁴
Advisory Committee	Clinical Chemistry
Clinical Trials	NCT01514292 ²⁵
Supplement Type	Real-Time Process
Supplement Reason	Change Design/Components/Specifications/Material
Expedited Review Granted?	No
Combination Product	No
Recalls	CDRH Recalls ²⁶

Approval Order Statement

Approval for updates to the G5 Mobile iOS App Software and G5 Mobile Transmitter Firmware for Dexcom's G5 Mobile Continuous Glucose Monitoring System. The App is being modified to: backfill data from the CGM if there are data gaps within the last 3 hours; include mute override settings, which allow users to hear alerts critical to safe and effective use of the device even when their smart device is muted or turned to a very low volume; and to correct software anomalies. The Transmitter Firmware is being modified to: transmit data for backfill in the App; improve efficiency of battery usage on the transmitter; expand transmitter database logging to include additional information; support internal engineering efforts; and to correct software anomalies.

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11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
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15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. [/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm](/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm)
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm>
22. </scripts/cdrh/cfdocs/cfpma/pma.cfm>
23. [/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P120005&SupplementType=NONE](/scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P120005&SupplementType=NONE)
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Page Last Updated: 11/06/2023

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13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. [/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm](/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm)
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>

19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfpma/pma.cfm
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