

**K191112 GEHC DXA Bone Densitometers with enCORE version
18**Sep 19, 2019
146 days to decisionK191112 · Product code: **KGI** · Radiology
Source: <https://www.510kdatabase.net/k191112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Apr 26, 2019
Decision date	Sep 19, 2019
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
Location	Wauwatosa, WI, US
Contact	Martha Kamrow
510(k) history	14 submissions · 14 cleared · 2016-2026

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