FDA 510(k) Premarket Notification

CLEARED

K983028 FRACTURE RISK OPTION FOR THE QDR BONE DENSITOMETER, MODEL#S QDR4500, QDR2000, QDR1500, QDR4000, QDR1000, QDR1000W

Nov 13, 1998
74 days to decision

K983028 · Product code: **KGI** · Radiology
Source: https://www.510kdatabase.net/k983028/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Densitometer, Bone (KGI)
Date received	Aug 31, 1998
Decision date	Nov 13, 1998
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hologic, Inc.**
Location	Waltham, MA, US
Contact	NANDINI MURPHY
Website	https://www.hologic.com/
510(k) history	115 submissions · 111 cleared · 1987-2025

Hologic, Inc. is a medical device company headquartered in Waltham, Massachusetts. The company specializes in women's health, diagnostics, and medical imaging technologies. Hologic has maintained a strong FDA 510(k) regulatory record since its founding in 1987. The company has received FDA 510(k) clearances from total submissions. Recent cleared devices span microbiology, radiology, and obstetrics & gynecology categories. The latest clearance in 2025 demonstrates continued active development and regulatory engagement. Hologic's cleared device portfolio includes molecular ...