FDA 510(k) Premarket Notification

K261132 Healium Intelliscan LX192LC

CLEARED

May 5, 2026
29 days to decision

K261132 · Product code: **IYN** · Radiology
Source: https://www.510kdatabase.net/k261132/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Apr 6, 2026
Decision date	May 5, 2026
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Healium Intelliscan Corporation**
Location	New York, Ny, NY, US
Contact	Biju Jacob
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Medicsense USA, LLC**
Contact	George Hattub

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov