

K260192 DIANA

Jul 24, 2026
183 days to decision

K260192 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k260192/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 22, 2026
Decision date	Jul 24, 2026
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	ROPCA ApS
Location	Odense M, DK
Contact	Trine Straarup Winther
510(k) history	2 submissions · 2 cleared · 2026-2026