K212851 EchoSK and EchoSGyn modules for EchoS Family devices

CLEARED

Mar 16, 2022
190 days to decision

K212851 · Product code: **IYO** · Radiology
Source: https://www.510kdatabase.net/k212851/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Sep 7, 2021
Decision date	Mar 16, 2022
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Echolight S.P.A**
Location	Lecce, IT
Contact	Giuseppe Criscenti
510(k) history	3 submissions · 3 cleared · 2018-2022