

K211863 eVolve PACSAug 12, 2021
57 days to decisionK211863 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k211863/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 16, 2021
Decision date	Aug 12, 2021
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Evolve Pacs, Inc.
Location	Dallas, TX, US
Contact	David Donahue
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	O Tech, Inc.
Contact	Carl Alletto

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

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