

K233826 KosmosAug 29, 2024
272 days to decisionK233826 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k233826/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 1, 2023
Decision date	Aug 29, 2024
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	EchoNous, Inc.
Location	Redmond, VA, US
Contact	Joshua Kim
510(k) history	5 submissions · 5 cleared · 2018-2025

CLINICAL EVIDENCE - NCT06027164**Kosmos Trio and Ejection Fraction Pivotal Study**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	153 patients (actual)
Study sites	1 site
Condition studied	Cardiac Disease
Study type	Observational
Completion date	May 16, 2024
Sponsor	EchoNous Inc. (Industry)

Primary outcome

Assessment of Global Left Ventricular Function

Secondary outcome

Assessment of Automatic Structure Labelling

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06027164