FDA 510(k) Premarket Notification

K203683 CarboClear Lumbar Cage System

CLEARED

Jan 15, 2021
29 days to decision

K203683 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k203683/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 17, 2020
Decision date	Jan 15, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Carbofix Orthpedics , Ltd.**
Location	Herzliya, IL
Contact	Hila Wachsler-Avrahami
510(k) history	2 submissions · 2 cleared · 2021-2023