

K160002 Piccolo Composite(R) Distal Volar Radius Plate System

Mar 9, 2016
65 days to decision

K160002 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k160002/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 4, 2016
Decision date	Mar 9, 2016
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CarboFix Orthopedics , Ltd.
Location	Herzliya, IL
Contact	Yael Rubin
510(k) history	32 submissions · 32 cleared · 2011-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160002/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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