

K261830 FRAXION 3.5 Plate System (Various - See Catalog)

Aug 28, 2026
87 days to decision

K261830 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k261830/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 2, 2026
Decision date	Aug 28, 2026
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FRAXION 4.5 Plate System (Various - See Catalog);FRAXION Mini Plate System (Various - See Catalog);FRAXION Bone Screw System (Various - See Catalog)

APPLICANT

Company	Ortler Global Tibbi Gerecler Anonim Sirketi
Location	Ankara, TR
Contact	TAHA CIBIR
510(k) history	1 submissions · 1 cleared · 2026-2026