

K230397 Cut Screw - Percutaneous Compression ScrewJun 12, 2023
118 days to decisionK230397 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k230397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 14, 2023
Decision date	Jun 12, 2023
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GM Dos Reis Industria e Comercio Ltda.
Location	Campinas, BR
Contact	Guilherme Esteves Pontes
510(k) history	13 submissions · 13 cleared · 2020-2026

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