

**K946165 CMF-TITANIUM CRANIO-MAXILLO-FACIAL
FRACTURE FIXATION (OSTEOSYNTHESIS) SYSTEM**May 23, 1995
155 days to decisionK946165 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k946165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 19, 1994
Decision date	May 23, 1995
Days to decision	155 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Elekta Instruments, Inc.
Location	Tucker, GA, US
Contact	THOMAS PARKER
510(k) history	8 submissions · 8 cleared · 1992-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k946165/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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