

**K973789 NORIAN CRANIAL REPAIR SYSTEM (CRS)BONE
CEMENT- 5CC KIT, NORIAN CRANIAL REPAIR SYSTEM (CRS)
BONE CEMENT- 10CC**

May 18, 1998
224 days to decision

K973789 · Product code: **GXP** · Neurology
Source: <https://www.510kdatabase.net/k973789/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Methyl Methacrylate For Cranioplasty (GXP)
Date received	Oct 6, 1997
Decision date	May 18, 1998
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Norian Corp.
Location	Menlo Park, CA, US
Contact	SUSANNE T SMITH
510(k) history	3 submissions · 3 cleared · 1988-1999

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Device record: <https://www.510kdatabase.net/k973789/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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