FDA 510(k) Premarket Notification

CLEARED

K110684 MEDCAD ACCUSHAPE (TM) PEEK PATIENT SPECIFIC CRANIAL / CRANIOFACIAL IMPLANT

Jun 24, 2011
105 days to decision

K110684 · Product code: **GXN** · Neurology
Source: https://www.510kdatabase.net/k110684/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Non-alterable (GXN)
Date received	Mar 11, 2011
Decision date	Jun 24, 2011
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vanduzen Dba Medcad**
Location	Richardson, TX, US
Contact	DIANE RUTHERFORD
510(k) history	1 submissions · 1 cleared · 2011-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k110684/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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