

K140367 ARCHITECT PX EXTRACELLULAR COLLAGEN MATRIXSep 12, 2014
210 days to decisionK140367 · Product code: **KGN** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k140367/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Feb 14, 2014
Decision date	Sep 12, 2014
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Harbor Medtech, Inc.
Location	Irvine, CA, US
Contact	JERRY MEZGER
510(k) history	2 submissions · 2 cleared · 2013-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140367/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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