FDA 510(k) Premarket Notification

CLEARED

K102944 CORELEADER HEMO-PAD MODEL CPII 02030

Sep 7, 2011
338 days to decision

K102944 · Product code: **QSY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k102944/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Oct 4, 2010
Decision date	Sep 7, 2011
Days to decision	338 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coreleader Biotech Co., Ltd.**
Location	Taipei, Taiwan, TW
Contact	IAN LI
510(k) history	9 submissions · 9 cleared · 2011-2015

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k102944/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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