

K152959 Sealapex tubes, Sealapex bulk package, Sealapex Xpress dual-barrel syringesApr 14, 2016
190 days to decisionK152959 · Product code: **KIF** · Dental
Source: <https://www.510kdatabase.net/k152959/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Resin, Root Canal Filling (KIF)
Date received	Oct 7, 2015
Decision date	Apr 14, 2016
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sybron Dental Specialties
Location	Newport Beach, CA, US
Contact	Courtney Clark
510(k) history	15 submissions · 15 cleared · 2006-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152959/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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