

K943421 ORTHODONITC ELASTOMERIC SLEEVINGMay 23, 1995
312 days to decisionK943421 · Product code: **DZD** · Dental
Source: <https://www.510kdatabase.net/k943421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Orthodontic (DZD)
Date received	Jul 15, 1994
Decision date	May 23, 1995
Days to decision	312 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Jon-Ko Products, Inc.
Location	San Diego, CA, US
Contact	STEPHEN M MARNELLA
510(k) history	5 submissions · 5 cleared · 1995-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 3, 2026