

K971848 TDK MEDICAL GRADE CD-RAug 15, 1997
88 days to decisionK971848 · Product code: **LMB** · Radiology
Source: <https://www.510kdatabase.net/k971848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Digital Image Storage, Radiological (LMB)
Date received	May 19, 1997
Decision date	Aug 15, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tdk Electronics Corporation of America
Location	Port Washington, NY, US
Contact	KOYO YOKOI
510(k) history	1 submissions · 1 cleared · 1997-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971848/> 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 May 20, 2026