

K142228 Heated Eye PadFeb 9, 2015
180 days to decisionK142228 · Product code: IRT · Physical Medicine
Source: <https://www.510kdatabase.net/k142228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pad, Heating, Powered (IRT)
Date received	Aug 13, 2014
Decision date	Feb 9, 2015
Days to decision	180 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Digital Heat Corporation
Location	Tempe, AZ, US
Contact	John Devine
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142228/> 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 June 5, 2026