

K152984 Disposable Concentric Needle electrodes, Disposable Monopolar Needle electrodes, Disposable EP Needle electrodes, Disposable Hypodermic Needle electrodes

Jun 3, 2016
238 days to decision

K152984 · Product code: **IKT** · Neurology
Source: <https://www.510kdatabase.net/k152984/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle, Diagnostic Electromyograph (IKT)
Date received	Oct 9, 2015
Decision date	Jun 3, 2016
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio Protech, Inc.
Location	Sparks, NV, US
Contact	DANIEL WOO
510(k) history	17 submissions · 17 cleared · 2002-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152984/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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