

K142775 Neuwater TM (HydrocynTM aqua)Feb 13, 2015
140 days to decisionK142775 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k142775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Sep 26, 2014
Decision date	Feb 13, 2015
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Vigilenz Medical Devices
Location	Bukit Minyak, MY
Contact	Shudipta Choudhury
510(k) history	1 submissions · 1 cleared · 2015-2015

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