

**K943470 BURNFREE BURNSOOTHE HYDROGEL BURN  
BLOTTS**Sep 27, 1994  
70 days to decisionK943470 · Product code: **MGQ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k943470/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Dressing, Wound And Burn, Hydrogel W/drug And/or Biologic (MGQ)
Date received	Jul 19, 1994
Decision date	Sep 27, 1994
Days to decision	70 days
Third-party review	No

**APPLICANT**

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Company	<b>Levtrade Intl. (Pty) , Ltd.</b>
Location	Petoria, South Africa, ZA
Contact	WILLIAM M KOPLOVSKY
510(k) history	4 submissions · 2 cleared · 1993-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943470/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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