

K813214 INFANT PHOTOTHERAPY MASKDec 9, 1981
30 days to decisionK813214 · Product code: **FOK** · General Hospital
Source: <https://www.510kdatabase.net/k813214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pad, Neonatal Eye (FOK)
Date received	Nov 9, 1981
Decision date	Dec 9, 1981
Days to decision	30 days
Third-party review	No

APPLICANT

Company	Montrose Phototherapy Supply
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1981-1981

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Device record: <https://www.510kdatabase.net/k813214/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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