

K812017 X-RAY DETECTABLE BANDNov 20, 1981
126 days to decisionK812017 · Product code: **GDY** · Radiology
Source: <https://www.510kdatabase.net/k812017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal, X-ray Detectable (GDY)
Date received	Jul 17, 1981
Decision date	Nov 20, 1981
Days to decision	126 days
Third-party review	No

APPLICANT

Company	Isramed, Inc.
Location	Mchenry, IL, US
510(k) history	3 submissions · 3 cleared · 1981-1982

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Device record: <https://www.510kdatabase.net/k812017/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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