

K143506 BIS STANDARD SENSOR,1-CHANNEL (3 ELECTRODES)Apr 16, 2015
127 days to decisionK143506 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k143506/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Dec 10, 2014
Decision date	Apr 16, 2015
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary
Other names	BIS PEDI SENSOR,1-CHANNEL,3 ELECTRODES; BIS QUATRO SENSOR; BIS PEDI-XP SENSOR,2-CHANNEL (4 ELECTRODES); BIS EXTEND SENSOR; BIS BILATERAL SENSOR,4-CHANNEL (6 ELECTRODES); BIS INSIGHT SENSOR,CVI-ENABLED,2-CHANNEL (4 ELECTRODES)

APPLICANT

Company	Covidien
Location	North Haven, CT, US
Contact	TIMOTHY HOLWICK
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...

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Device record: <https://www.510kdatabase.net/k143506/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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