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# Medical Device News and Insights

## [Safety Assurance Cases and Medical Device 510\(k\) Submissions](#)

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Recently, the FDA has been highlighting the upcoming call for certain [510\(k\) medical device submissions to include safety assurance cases](#). This has left many medical device manufacturers curious as to what information they will need to include when putting together a safety assurance case for their products, as well as how to structure a safety assurance case that will best meet [FDA requirements](#). 5 retweet

In order to get a better idea of what the FDA is expecting from future 510(k) safety assurance case submissions, it is helpful to examine a segment of the medical device industry that has been the focus of recent assurance case attention. Infusion pump manufacturers have been operating under the [Infusion Pump Improvement Initiative](#) since April of 2010, a program that FDA designed specifically to [help medical device companies analyze potential hazards](#) associated with a wide variety of potential use situations for [infusion pump devices](#).

The result of this in-depth analysis is a safety assurance case that [effectively describes the evidence available](#) to prove that the [medical device](#) in question is safe considering both the risks it presents and the complexity of the system overall. It is helpful to think of a safety assurance case as a type of “road map” that walks readers through the claims made by the device manufacturer, the manufacturer’s arguments to support those claims, and finally, the data and evidence available to reinforce those arguments.

Each safety assurance case must satisfy each of the following points to be effective:

- Make an explicit set of claims about the system
- Produce the supporting evidence
- Provide a set of arguments
- Make clear the assumptions and judgments underlying the arguments
- Allow different viewpoints and levels of detail

Currently, safety assurance cases are not considered a mandatory aspect of the [510\(k\) process](#). However, making use of a safety assurance case can help a company to better communicate the safety and effectiveness of a medical device to the FDA and potentially reduce the duration and complexity of the clearance process. By taking a more active approach to risk management, the FDA hopes to use safety assurance cases as an important tool to streamline the 510(k) review and clearance process.

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Tags: [510\(k\) review process](#), [510k submissions](#), [FDA](#), [FDA device approval](#), [FDA Infusion Pump Improvement Initiative](#)

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