

Reporter	What to report	Report form	To whom	When
Manufacturers	Deaths, serious injuries, malfunctions	Form FDA 3500A	FDA	Within 30 calendar days of becoming aware of the event
	Events that require action to prevent risk of substantial harm to the public health, events designated by the FDA	Form FDA 3500A	FDA	Within 5 working days of becoming aware of the event
Importers	Deaths, serious injuries	Form FDA 3500A	FDA and manufacturer	Within 30 calendar days of becoming aware of the event
	Malfunctions	Form FDA 3500A	Manufacturer	Within 30 calendar days of becoming aware of the event
User facilities	Device-related death	Form FDA 3500A	FDA and manufacturer	Within 10 working days of becoming aware of the event
	Device-related serious injury	Form FDA 3500A	Manufacturer OR FDA if manufacturer is unknown	Within 10 working days of becoming aware of the event
	Annual summary	Form FDA 3419	FDA	January 1st for the preceding year

# Nonresponders Fda Report Medical Device

**Xiaolong Qi**



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