



FDA report “This guidance provides recommendations to manufacturers, FDA reviewers, and other entities involved in manufacturing devices that contain small-bore connectors designed for enteral feeding, as well as those submitting or reviewing premarket notification submissions [510(k)s] for these devices. Small-bore connectors provide a mechanism for the connection between a variety of medical devices including those with enteral and non-enteral (e.g., intravenous) applications. The use of common connector designs, such as Luer connectors, has led to unintended connections between devices that have different intended uses and has resulted in serious and sometimes fatal consequences to patients”.

Guidance to mitigate the risks of misconnections with small-bore enteral connectors  
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