

Executive Summary

This advisory panel will address concerns related to a specific subset of jet injectors known as MUNJIs or Multiple-Use Nozzle Jet Injectors. A jet injector is a device that uses high-pressure to inject fluid through the skin without the use of a needle. Jet injectors are Class II devices regulated through the 510(k) process and must demonstrate substantial equivalence to devices previously marketed in the United States. MUNJIs differ from other jet injectors because the fluid path for the injection is used more than once. The concerns relating to MUNJIs do not pertain to jet injectors that are either single-use or labeled and sold for only one patient. There are two intended uses for MUNJIs: those intended for 1) immunization and 2) administering anesthesia during dental procedures. Some benefits from MUNJI use over traditional needles and syringes include high delivery rates, no re-use of contaminated needles, and a reduction in the volume of clinical waste.

The principal concern relating to MUNJI use is the potential for disease transmission when a jet injector nozzle is contaminated with infected blood or serum during an injection. When contamination of the MUNJI occurs on the skin-contacting surface of the jet injector or in the fluid path, the residual infected blood or serum can be injected into the subsequent patient potentially infecting that patient with a blood borne disease. The only documented case of cross-contamination between jet injections was a hepatitis outbreak in 1985 at a California weight loss clinic. Although this is the only documented case in humans, in vivo animal studies and bench laboratory studies link these devices to disease transmission. The Food and Drug Administration has received one medical device report relating to MUNJI reuse; however, this was a case of misuse, and the report did not result in a documented adverse event.

In order to address the MUNJI cross-contamination concern, manufacturers have tried to develop safer means of administering injections. However, there remain challenges to evaluating the potential for disease transmission and whether recent design improvements to MUNJIs have eliminated or adequately reduced the potential for cross-contamination. This panel will focus on whether it is possible to assess the cross-contamination risk associated with MUNJIs.