

## **Clear SOUP and COTS Software for Medical Device Development**

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In many industries, manufacturers have reduced development times by using COTS (commercial-off-the-shelf) software and hardware. Pressures to bring new, feature-rich products to market quickly affect medical device manufacturers as much as anyone, but the industry may be reluctant to follow suit due to well-justified concerns that COTS implies SOUP (software of uncertain provenance), and thus may compromise device safety and pre-market approval by the FDA and other regulatory agencies.

While we should indeed exercise diligence and caution when considering COTS software for medical devices, COTS software may be perfectly acceptable, given stringent selection criteria, and appropriate and equally stringent validation of the completed systems and devices. If we make the distinction between opaque SOUP and clear SOUP, that is, SOUP for which source code, fault histories and long in-use histories are available, we will find that COTS software may be the optimal choice for many safety-related medical devices.

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