

Devices & Diagnostics Letter

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FDA Warns Storz Medical for Claims on Website

Storz Medical has removed the D-Actor 50 from its online product offerings following an FDA warning letter that claimed the device had not been cleared or approved for marketing.

The letter also cites the Swiss company, which is a member of the Karl Storz Group, for off-label claims made on its website for the D-Actor 200 device. The pulse-activation device is cleared to temporarily increase local blood circulation and relieve minor muscle aches and pains.

But the company website claimed the device could be used for tissue purification and to improve the interaction between the central and peripheral nervous systems, according to the April 8 warning letter posted last week.

"These statements represent a major change or modification in the intended use of your device that require a new premarket notification," the letter says.

The company has removed the claims for the D-Actor 200 from its website. It did not respond to a request for comment by press time.

The warning letter is available at

www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm210845.htm. — Virgil Dickson

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