

Judges side with FDA in rejecting stem cell device

March 22 2013

(AP)—A federal appeals court is siding with the Food and Drug Administration in a case brought by medical device maker Cytori, ruling that the agency was correct to reject fast-track approval for two company devices used to process adult stem cells.

Cytori makes the Celution and StemSource devices which separate [adult stem cells](#) from fat tissue using a combination of spinning motions and [chemical reactions](#). The company asked the FDA to approve the devices using a fast-track pathway reserved for devices that are similar to products already on the market. Cytori argued that its devices are similar to devices used to process blood and bone marrow.

A three-judge panel said the FDA was right to reject that argument and to require the company to apply through a more rigorous process.

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Citation: Judges side with FDA in rejecting stem cell device (2013, March 22) retrieved 2 May 2024 from <https://medicalxpress.com/news/2013-03-side-fda-stem-cell-device.html>

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