

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.

Copyright 2013 The Associated Press. All rights reserved. This material may not be published, broadcast, rewritten or redistributed.

Citation: Judges side with FDA in rejecting stem cell device (2013, March 22) retrieved 19 April 2024 from <https://medicalxpress.com/news/2013-03-side-fda-stem-cell-device.html>

<p>This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.</p>
--