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Japan's new medical device receives FDA nod

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Singapore: The US FDA has recently given its approval for a device that treats dialysis-related amyloidosis (DRA), a complication of dialysis used to treat kidney failure. DRA is a rare and chronic complication caused by buildup of a protein called beta-2-microglobulin.

The newly approved device, Lixelle Beta 2-microglobulin Apheresis Column, is the first device that can remove protein from the blood using porous cellulose beads, said the FDA in its press release. The device has been evaluated for performance in clinical trials conducted in 100 patients in Japan.

The agency has also ordered the Japanese device maker Kaneaka Corp. to conduct post-approval studies to assess the device's benefits, risks and side effects among US volunteers. Dialysis-related amyloidosis most often occurs in patients with kidney failure, especially adults older than 60, who have been on hemodialysis for more than five years.

The device is manufactured by a Japanese device maker Kaneaka Corp and will be distributed in the US through the company's subsidiary Kaneka Pharma America. "While DRA affects only a small population of patients on dialysis, there are not many treatment options for these patients and some options may not be available to patients in all areas," said Mr William Maisel, MD, MPH, deputy director for science, chief scientist and acting director of the Office of Device Evaluation in FDA's Center for Devices and Radiological Health.