This is a brief overview of information related to FDA’s approval to market this product. See the links below to the Summary of Safety and Probable Benefit (SSPB) and product labeling for more complete information on this product, its indications for use, and the basis for FDA’s approval.

**Product Name:** Lixelle Beta 2-microglobulin Apheresis Column  
**HDE Applicant:** Kaneka Pharma America LLC  
**Address:** 546 Fifth Avenue, 21st Floor, New York, NY 10036  
**Approval Date:** March 5, 2015  
**Approval Letter:** [http://www.accessdata.fda.gov/cdrh_docs/pdf13/h130001a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf13/h130001a.pdf)  

What is it? The Lixelle Beta 2-microglobulin Apheresis Column (Lixelle Column) is a device that treats dialysis-related amyloidosis, a complication of kidney failure. The Lixelle Column contains specialized beads that remove a protein called Beta 2-microglobulin from the blood.

How does it work? The Lixelle Column is added to the blood-tubing set during dialysis treatment. As the blood passes through the Lixelle Column, the beads remove Beta 2-microglobulin. These beads contain tiny pores that can remove Beta 2-microglobulin from the blood while keeping essential proteins. Treatment is usually three times a week.

When is it used? The Lixelle Column can be used in patients with dialysis-related amyloidosis (DRA).

DRA is a rare disorder caused by the buildup of Beta 2-microglobulin in tissue. In patients with reduced kidney function, the body does not adequately clear Beta 2-microglobulin. This leads to an increase of Beta 2-microglobulin in the blood and tissues. Tissue deposit of Beta 2-microglobulin is sometimes associated with conditions such as joint pain or stiffness, carpal tunnel syndrome, bone cysts, and bone fractures. DRA is a chronic, developing condition that generally gets worse as the years on dialysis increase due to the accumulation of Beta 2-microglobulin.

A kidney transplant may reduce Beta 2-microglobulin levels back to normal and improve symptoms over time. Beta 2-microglobulin levels may also be reduced by using modified dialysis treatments (such as high flux dialysis membranes, hemodiafiltration, or night-time hemodialysis). High flux dialysis membranes are used in the U.S., but hemodiafiltration and night-time dialysis are not widely available. Other treatments, which are focused on pain reduction, include surgical removal of diseased tissues (carpal tunnel release, joint replacement, and shoulder surgery).

What will it accomplish? The Lixelle Column has been studied in numerous small clinical trials with results published in the literature. These articles describe the treatment of approximately 100 patients with DRA in Japan. Based on these studies, the device may:

- reduce Beta 2-microglobulin in the blood.
- improve grip/pinch strength and motor nerve terminal latency with carpal tunnel syndrome.
• decrease bone cyst formation and size.
• reduce joint pain/stiffness and nighttime awakening.
• improve activities of daily living (ADL) scores.

The probable benefit appears to continue during the course of treatment with the device.

**When should it not be used?** The device should not be used in:

• patients who are unable to have their blood “thinned” for dialysis therapy, such as those with severe anemia, severe bleeding disorders, severe stomach ulcers, or who are receiving blood-thinning medications for any reason.

• patients who are unable to tolerate removal of blood from the body during dialysis therapy, such as those with severe cardiac insufficiency, severe heart attack, severe irregular heartbeat, acute seizure disorder, or severe, uncontrolled high or low blood pressure.

• patients who have had allergic reactions to heparin or patients who have had allergic reactions to the device.

**Additional information:** The Summary of Safety and Probable Benefit and labeling [are available online](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=h130001).
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