FDA approves cervical disk device

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The U.S. Food and Drug Administration Tuesday announced approval of the first device designed to treat cervical degenerative disc disease.

The Prestige Cervical Disc, manufactured by Medtronic Sofamor Danek of Memphis, is used to treat one of the most common causes of neck and arm pain.

"The approval of this artificial disc means that people with cervical degenerative disc disease now will have another surgical option for treating this condition," said Dr. Daniel Schultz, director of the FDA's Center for Devices and Radiological Health. "This device will help relieve pain and restore function."

The FDA said current surgical treatments involve removing a diseased or bulging disc in a patient's neck and fusing two or more bony vertebrae. The Prestige Cervical Disc allows the option of replacing the impaired natural disc.

The FDA said it based its approval on the company's laboratory and animal testing, and on its clinical study of 541 patients.

As a condition of approval, the company will conduct a post-approval study during the next seven years to evaluate the longer term safety and effectiveness of the device.

The Prestige Cervical Disc was approved as a class III, or high-risk, device.