LDR Receives FDA Approval for the Mobi-C Cervical Disc for One-Level Use

LDR

First mobile-bearing, bone-sparing cervical disc approved in the US market

LDR, a privately held medical device company offering exclusive spinal implant technologies for both non-fusion and fusion applications, today announced that it has received a letter of approval from the U.S. FDA allowing the commercial sale and distribution of the Mobi-C® Cervical Disc (Mobi-C), for one-level indications in the United States.

“We are pleased that the FDA, after an intensive review of our Pre-Market Application (PMA), has determined that Mobi-C is safe and effective for one-level cervical disc replacement in theUnited States,” said Christophe Lavigne, President and CEO of LDR. “The data from our study represents the latest Level I evidence supporting cervical disc replacement as an attractive treatment alternative to anterior cervical discectomy fusion (ACDF) for indicated patients. This approval is validation that LDR continues to introduce innovative and exclusive spine technologies designed to improve patient care.”

Mobi-C is a cobalt chromium alloy and polyethylene, mobile-bearing prosthesis specifically designed as abone-sparing, cervical intervertebral disc replacement. In addition to the unique mobile-bearing feature, Mobi-C offers a simplified surgical technique as compared to other commercially availabledevices.

In the one-level arm of the Investigational Device Exemption (IDE) trial, Mobi-C demonstrated non-inferiority in overall trial success compared to ACDF, which is a standard option for treating degenerative disc disease. Other findings comparing Mobi-C to ACDF in the one-level arm at the 24-month endpoint included:

- Mobi-C implanted at one-level demonstrated non-inferiority in overall trial success compared to ACDF. The difference between Mobi-C’s overall success rate of 73.7% and ACDF’s rate of 65.3% represented statistical non-inferiority (p=0.0021).
- The rate of secondary surgery at the index level for Mobi-C was 1.2% versus 6.2% for ACDF.
- The percentage of subjects who reported negative radiographic changes from baseline in adjacent segments was:
    - At the inferior adjacent level; 7.7% of Mobi-C patients compared to 21.0% of ACDF patients
    - At the superior adjacent level; 14.6% of Mobi-C patients compared to 25.0% of ACDF patients
- Mean return to work time was 29.3 days for Mobi-C compared to 36.8 days

for ACDF.
- Mobi-C is a safe and effective surgical option at one-level in the cervical spine from C3-C7 for indicated patients.

"We are very proud to be one of the few companies to have successfully obtained FDA approval for a cervical artificial disc device with one-level indications. I want to thank those involved in this study for their incredible support, especially the patient participants," continued Lavigne. "We are now starting our US Mobi-C training and education program for surgeons, and are very excited to enter this market. Mobi-C is now the only cervical disc available to non-captive, independent U.S. sales agents, giving them the unique ability to strengthen their presence with their customers."

"The data from the one-level Mobi-C trial adds to the extensive library of evidence supporting cervical disc replacement as an attractive alternative to anterior cervical fusion," said Dr. Michael Hisey of the Texas Back Institute, Plano, Texas. "I am very pleased now that Mobi-C is approved for one-level indications, as I will have the opportunity to offer my patients a state-of-the-art treatment option that will address their symptoms while providing the potential to maintain normal spinal motion."

In addition to the full approval of Mobi-C for one-level indications, LDR previously received an approvable letter for Mobi-C for two-level indications on October 26, 2012. The two-level PMA is continuing through the review process with the FDA.