OVERVIEW

OP-1 Putty is an osteoinductive and osteoconductive material that consists of recombinant human Osteogenic Protein (rhOP-1), Type I Bovine Bone Collagen Matrix (collagen matrix) and the Putty Additive Carboxymethylcellulose (CMC). This Premarket Approval Application (PMA) seeks approval for use of OP-1® Putty for posterolateral lumbar spinal fusion in patients with spondylolisthesis who have failed at least 6 months of conservative non-surgical treatment.

Research into bone morphogenetic proteins (BMPs) for orthopedic applications began over 40 years ago with Marshall Urist’s discovery in 1965 that a protein present in bone matrix is responsible for osteoinduction. Urist, along with colleagues Johnson and Finerman at University of California at Los Angeles, demonstrated that purified human BMPs could successfully treat resistant non-unions and partial or complete long bone segmental defects and lumbar pseudarthrosis with a combination of BMP and autograft.

Two recombinant human BMPs are currently available in the United States, rhBMP-2 (Infuse, Medtronic Sofamor Danek, Memphis, TN) and rhBMP-7 (OP-1, Stryker Biotech, Hopkinton, MA). Both have been well characterized in animal studies and reported in scientific literature with over 700 citations on OP-1 alone. They have been studied in over 800 patients in clinical trials, including fracture, non-union, and spinal applications. OP-1 represents the first in class availability of a BMP with commercial approval in 2001. Since that time, over 339,000 patients in the United States have been treated with BMPs for orthopedic applications.

The OP-1 clinical program presented here was designed to evaluate the safety and effectiveness of OP-1 Putty as a replacement to autograft in posterolateral fusion (PLF) of the lumbar spine in patients with degenerative spondylolisthesis with spinal stenosis. Iliac crest bone autograft is currently the standard-of-care in PLF, but OP-1 Putty offers a desirable alternative. The inherent risks associated with iliac donor site surgery include persistent pain as well as less common but potentially catastrophic complications such as arterial and nerve damage. Furthermore, complications due to autograft harvest are more likely in the elderly, the obese, and those with underlying medical conditions.

This PMA presents valid, scientific evidence of the safety and effectiveness of OP-1 Putty in PLF, as compared to the current standard of care, iliac crest autograft.

References


