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510(k) Summary

Trade/Proprietary Name: Wright Plaster of Paris Bone Void Filler Kit
 Common Name: Calcium Sulfate
 Product Classification: Unclassified
 Predicate Device: Wright Plaster of Paris Pellets

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description/Intended Use

Wright Plaster of Paris Bone Void Filler Kit contains calcium sulfate powder and saline in premeasured quantities, so that when mixed together in the mixing bowl provided, then placed into the mold provided, the mixture sets to form Wright Plaster of Paris Pellets. The biodegradable, radiopaque pellets are resorbed in 30-60 days when used according to labeling. The kit is provided sterile for single patient use.

Wright Plaster of Paris Pellets are intended to be gently packed into non-loadbearing voids in long bone. These bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The pellets provide a bone void filler that resorbs and is replaced with bone during the healing process.

Material

When mixed according to directions, the kit produced calcium sulfate (plaster of Paris) pellets.

Testing Summary

Dissolution studies demonstrate Wright Plaster of Paris Bone Void Filler Kit to possess equivalent dissolution rates to the predicate device. Mechanical testing demonstrated the cast pellets have a compressive failure rate substantially equivalent to the compressed pellets and to trabecular bone. Testing indicates the cast pellets have a mass/volume ratio within 15% of the compressed pellets. Testing indicates the product to be non-pyrogenic following the calcining process.