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WRIGHT
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510(k) Summary of Safety and Efficacy

Trade/Proprietary Name: Wright Plaster of Paris Pellets
Common Name: Calcium Sulfate Dihydrate
Product Classification: Unclassified
Predicate Devices: Plaster of Paris Pellets (Ethicon)

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 Pellets are provided sterile for single patient use. The biodegradable, radiopaque pellets are resorbed in 30 to 60 days when used according to labeling. Wright Plaster of Paris Pellets are 0.1g each and are supplied in pouches of 100 pellets.

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

Material

Wright Plaster of Paris Pellets are made of 98% medical grade calcium dihydrate ($\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$) and 2% stearic acid.

Testing Summary

Dissolution studies demonstrate Wright Plaster of Paris Pellets to possess equivalent dissolution rates to the predicate device.