

MAY - 7 1997

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**WRIGHT**

MEDICAL TECHNOLOGY, INC.

5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971**510(k) Summary**

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

(a) (1) Submitter's name: Wright Medical Technology, Inc.
Submitter's address: 5677 Airline Road, Arlington, Tennessee 38002
Submitter's telephone number: 901/867-9971
Contact person: Robert Churinetz
Date summary prepared: May 6, 1997

(2) Trade or proprietary device name: Wright Plaster of Paris Pellets
Common or usual name: Calcium sulfate
Classification name: Unknown

(3) Legally marketed predicate device: Plaster of Paris Pellets (Ethicon)

(4) Subject device description:

Wright Plaster of Paris Pellets are provided sterile for single patient use. The biodegradable, radiopaque pellets are resorbed in approximately 30-60 days when used according to labeling. Wright Plaster of Paris Pellets are made of medical grade calcium sulfate and stearic acid (as a tableting aid).

(5) Subject device intended use:

Wright Plaster of Paris Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Wright Plaster of Paris Pellets are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects 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. Because the pellets are biodegradable and biocompatible, they may be used at an infected site.

(6) Technological characteristics:

The new device and the predicate device as described in (a) (3) are identical. In summary, the subject device has the same technological characteristics (i.e., design, material, and chemical composition) when compared to the predicate device.

(b) Performance data

Since a determination of substantial equivalence was not based on an assessment of performance data, no performance data was submitted.