510(k) SUMMARY

General Company Information

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General Device Information

Product Name: MONTAGE Settable, Resorbable Bone Putty

Common Name: Calcium Phosphate Cement

Classification: Class II
Product codes: GXP
Regulation: 21 CFR 882.5300

Predicate Device

Stryker Stryker Injectable Cement
[510(k) Number K060763]

Device Description

MONTAGE Settable, Resorbable Bone Putty is a sterile, biocompatible, resorbable material for use in repair of cranial defects. The MONTAGE device comprises two separate components of putty consistency containing granular calcium phosphate, calcium stearate, vitamin E acetate, a triglyceride, a polyalcohol and a mixture of a lactide-diester and polyester-based polymers. When mixed together, the components of the MONTAGE device form a putty-like material. The resulting hardened, resorbable material is primarily calcium phosphate. MONTAGE components must be mixed immediately prior to use.

Indications for Use

Orthocon MONTAGE Settable, Resorbable Bone Putty is a self-setting calcium phosphate cement indicated for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects with a surface area no larger than 25cm^2. MONTAGE Settable, Resorbable Bone Putty should be used only in skeletally mature individuals.

The following table shows comparisons of characteristics of MONTAGE Settable, Resorbable Bone Putty and the predicate device.

SUBSTANTIAL EQUIVALENCE INFORMATION

Orthocon, Inc. MONTAGE Settable, Resorbable Bone Putty 510(k) – 221933	**Stryker Injectable Cement HydroSet 510(k) - K060763**

Comparisons of Technological Characteristics

Device is intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects with a surface area no larger than 25cm^2.	Stryker Injectable Cement is intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects.
At the time of application, device is in the form of a putty-like material	At the time of application, device is in the form of a paste-like material
Device is designed to be manually applied to the cranial defect	Device is designed to be manually applied to the cranial defect
MONTAGE Settable, Resorbable Bone Putty is formulated as a two-part putty/putty device that forms a “settable” (hardening) material when manually mixed at the time of surgery	Stryker Injectable cement is formulated as a two-part powder/liquid device that forms a “settable” (hardening) material when manually mixed at the time of surgery
Sterile mixture of two separate components of putty-like consistency comprised of granular calcium phosphate, (hydroxyapatite and β-tricalcium phosphate), calcium stearate, vitamin E acetate, triacetin, 1,4-butanediol and a mixture of a lactide-diester and polyester-based (lactide and caprolactone) absorbable polymers. MONTAGE is to be mixed immediately prior to use. Resulting settable material from the two putties is primarily comprised of calcium phosphate .	Sterile mixture of two separate components, a powder comprised of dicalcium phosphate dihydrate, tetracalcium phosphate and tri-sodium citrate; and a liquid comprised of sodium phosphate, polyvinylpyrrolidone and water. Stryker Injectable Cement is to be manually mixed immediately prior to use. Resulting settable material from the two components is primarily comprised of calcium phosphate.

Implanted device is resorbable in greater than 30 days primarily due to presence of calcium phosphate.	Implanted device is resorbable in greater than 30 days primarily due to presence of calcium phosphate.
Single-patient-use device is provided sterile by gamma irradiation	Single-patient-use device is provided sterile by gamma irradiation and ethylene oxide
The bone putty is available in individual and/or multi-pack patient use sizes of up to 5cc (approximately 10 grams).	The device is available in individual; and/or multi-pack patient use sizes of 3, 5, 10 and 15cc.
Each putty is placed into a separate inner foil “blister” which are contained within a single outer foil pouch. The outer foil pouch contains a desiccant. The inner blister and outer pouch are heat sealed and sterilized.	Each kit contains one liquid-filled glass syringe and one plastic bowl of powder packaged within a double pre-formed tray with a Tyvek lid.
Mixing for homogeneity takes 45 sec.	Mixing for homogeneity takes 45 sec.
Material is settable within 10 minutes of application	Material is settable within 10 minutes of application
Material provides a working time of 2 minutes.	Material provides a working time of 2 minutes.
Device cures with no appreciable exothermic reaction.	Device cures with no appreciable exothermic reaction

Performance Data

Biocompatibility Testing

Testing was conducted to evaluate the device’s biocompatibility in accordance with the recommendations of ISO 10993. The following biocompatibility studies were conducted on the final, finished, gamma-irradiation sterilized device and in accordance with the GLP requirements: cytotoxicity, irritation, sensitization, systemic toxicity, genotoxicity, local tissue toxicity, hemolysis, pyrogenicity and neurotoxicity.

Bench Testing

Test	Description	Conclusions
Visual Inspection	Evaluated putty component color using a 3-point scale	Putty color and handling met specification
Putty Handling	Evaluated putty stickiness to gloves using a 3-point scale	
Putty Stiffness	Measured putty stiffness using a Penetrometer	Putty stiffness met specification
Putty Vitamin E Acetate Concentration	Solvent extraction and chemical analysis	Putty vitamin E acetate concentration met specification
Hand Mixing Time	Evaluated hand-mixing time using a 2-point scale	Mixing time, stickiness, and mixability met specification
Hand Mixing Stickiness	Evaluated stickiness to gloves using a 3-point scale	
Mixability	Evaluated mixability using a 2-point scale	
Device Stiffness	Measured device stiffness using a Penetrometer	Device stiffness met specification
Package Gross Leak	Bubble emission leak test	All test articles passed
Temperature Sensitivity	Determined maximum temperature increase observed during mixing	Acceptable maximum temperature increase following hand-mixing
Water Uptake, Swelling and Dissolution	Measured volume and mass changes during 72 hours in phosphate buffered saline, pH 7.4, at 37°C	Acceptable water uptake, swelling and dissolution

In-Vivo Testing

In-vivo animal testing was used to demonstrate substantial equivalence of MONTAGE Settable, Resorbable Bone Putty in the repair of a critical sized cranial bone defect of New Zealand White rabbits compared to the predicate device. Substantial equivalence was assessed from histopathologic evaluation and histomorphometric measurements of implant absorption over time.

Clinical Testing

No clinical studies have been conducted in support of this 510(k).

Conclusions

This submission supports the position that Orthocon MONTAGE Settable, Resorbable Bone Putty is substantially equivalent to the predicate device.

The information provided establishes that similar legally marketed devices have been used for the same clinical applications as Orthocon MONTAGE Settable, Resorbable Bone Putty and that Substantial Equivalence to the predicate device has been established. Each of the tests conducted passed the requirements as stated in the protocols and in recognized standards. The data presented demonstrate that the device is suitable for its indicated use. The materials from which the Orthocon device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.