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LIFECORE BIOMEDICAL

K961511

510(k) SUMMARY

JUN 28 1996

1.1 Manufacturer's Name:

Lifecore Biomedical Inc.
3515 Lyman Blvd.
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1.2 Date Prepared: April 8, 1996

1.3 Device Name: HAPSET hydroxylapatite/calcium sulfate plaster

1.4 Common Name: Prosthesis, Facial augmentation implant

1.5 Classification: Implant for cheek and chin, facial/cranial contour filling and bone augmentation for use with oral-maxillofacial fracture reduction procedures.

1.6 Substantially Equivalent Devices:

Prosthesis, Chin, Internal
- Implantech
- Interpore
- Vitek

Mesh, Surgical, Polymeric
- Davol
- Ethicon
- Gambro
- W.L. Gore and Associates

Prosthesis, PTFE/Carbon Fiber
- Vitek

Polytetrafluoroethylene Vitreous Carbon Materials for Maxillofacial Reconstruction
- Biomet
- Kimberly-Clark

Deminieralized Bone Graft products
- Grafton
- Tissue Bank sources

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1.7 Device Description

HAPSET consists of hydroxylapatite particulate which is supplied dry, in a mixing cup with medical grade calcium sulfate. The dry material is packaged with a diluent in a separate syringe that is used to mix with the hydroxylapatite/calcium sulfate. The resulting product is a paste-like plaster that is delivered with the appropriate instruments to the prepared surgical site and molded to the desired contours.

1.8 Intended Use:

HAPSET is intended for use in facial reconstructive surgery as a paste implant that will set up into a solid block implant of hydroxylapatite and medical grade calcium sulfate. This hydroxylapatite block serves to correct contour defects of facial structures such as chin, mandible, malar region, and maxilla.

1.9 Technological Characteristics:

HAPSET is manufactured from hydroxylapatite particles and medical grade calcium sulfate. The hydroxylapatite particles are chemically equivalent to the hydroxylapatite blocks commercially distributed for the same intended use. Other substantially equivalent devices with the same intended use are manufactured from materials such as silicone, PTFE, PTFE with carbon fibers, and vitreous carbon. Hydroxylapatite and medical grade calcium sulfate are known to be biocompatible and non-toxic which is an advantage over some of the other materials currently available.

1.10 Nonclinical Test:

HAPSET has been found to be non-toxic, non-irritating, and non-hemolytic. This is the same or an improvement over the toxicological profiles of the other material available for this intended use.

1.11 Clinical Test:

Reports in the literature indicate that the use of hydroxylapatite particles for aesthetic and medical augmentation have been successful since at least 1985. Clinicians are reporting that the implanted hydroxylapatite is biocompatible, stable and provides successful augmentation. The only reported drawback of the hydroxylapatite particles has been migration of the particles. HAPSET, in its plaster form, stabilize the particles and lessen the opportunity for particle migration by the setting of the implant into a solid block implant.

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Further, HAPSET has been commercially distributed by Lifecore since 1991, cleared for marketing by 510(k) K910432. No side effects, adverse events or toxic symptoms have been reported to date according to Lifecore and MDR databases. The HA-500 portion of HA is commercially marketed under 510(k) K842163 and K852766. Calcium Sulfate is marketed under the trade name CAPSET and was cleared to market via K943186 and K955096. All of these related devices have been shown in the medical industry to be non-toxic, safe and effective for the intended use on the product labeling.

1.12 Conclusions:

HAPSET, when used according to labeled directions, provides an implant that is substantially equivalent to hydroxylapatite blocks and other facial implants as noted. It is biocompatible and has demonstrated clinical safety and effectiveness for the same intended use as the current labeling applications listed. HAPSET use is being expanded for indications that include augmentation of the chin or cheek , for correcting of contour defects such as those created during autogenous bone grafting, and fracture reduction.