

JUN 23 2005

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Synthacer® and Syntricer® Calcium Salt Bone Void Filler(s)**

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of Synthacer® and Syntricer® is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

**MedArtis AG
Medizinprodukte and Forschung
Gabriel-Max-Str. 3
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Germany**

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Date Prepared: June 20, 2005

Contact Person:

Knut Hülse, Ph.D.

Phone: +41 71 694 5585
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Name of Device and Name/Address of Sponsor

1. Synthacer® Calcium Salt Bone Void Filler
2. Syntricer® Calcium Salt Bone Void Filler

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Gabriel-Max-Str. 3
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Classification Name

The submitted resorbable calcium salt bone void filler is a Class II product with the associated regulation and product code.

<i>MedArtis Product</i>	<i>Product Name</i>	<i>Regulation</i>	<i>Code</i>
Synthacer® Calcium Salt Bone Void Filler	Synthacer®	888.3045	MQV
Syntricer® Calcium Salt Bone Void Filler	Syntricer®	888.3045	MQV

Predicate Devices

Trade Name	Pore-Si Bone Graft Substitute/Apapore Bone Graft Substitute: Apatech LTD	Vitoss™ Scaffold Synthetic Cancellous Bone Void Filler: Orthovita
Common Name	Bone Void Filler	Bone Void Filler

Device Description

Synthacer® Calcium Salt Bone Void Filler is a porous calcium phosphate bone void filler for the repair of bony defects. It is an osteoconductive porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. Pore diameter averages 600µm and the average porosity is 60 – 80%. The implant is provided sterile in block, cylinder, morsel and ball form. Synthacer® is composed of a calcium phosphate ceramic which is at least 95% pure hydroxyapatite $\text{Ca}_5(\text{PO}_4)_3\text{OH}$.

Synthacer® promotes three-dimensional regeneration of bone in the defect site into which it is implanted. When Synthacer® is placed in direct contact with viable host bone, new bone growth occurs in apposition to the calcium phosphate surfaces of the implant. As the Synthacer® is resorbed, bone grows into the space previously occupied by the scaffold the implant provides. Synthacer® is radiopaque.

Syntricer® Calcium Salt Bone Void Filler is intended only for use as a bone void filler for voids or gaps in bone that are not intrinsic to the stability of the bony structure. Syntricer® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury. Syntricer® should not be used to treat large defects that in the surgeon's opinion would not heal spontaneously. Pore diameter averages 600µm and the average porosity is 60 – 80%. Syntricer® is composed of a calcium phosphate ceramic which is at least 95% pure tri-calcium phosphate $\text{Ca}_3(\text{PO}_4)_2$. The implant is provided sterile in block, cylinder, morsel and ball form.

Syntricer® is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). Following placement in the bony void, the Syntricer® will slowly resorb and be replaced with bone over time during the healing process.

Intended Use

Synthacer® Calcium Salt Bone Void Filler is intended only for use as a bone void filler for voids or gaps in bone that are not intrinsic to the stability of the bony structure. Synthacer® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury.

Syntricer® Calcium Salt Bone Void Filler is intended only for use as a bone void filler for voids or gaps in bone that are not intrinsic to the stability of the bony structure. Syntricer® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury.

Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, Synthacer® Calcium Salt Bone Void Filler and Syntricer® Calcium Salt Bone Void Filler and the predicate devices are substantially equivalent and have the same intended use. Based on the technological characteristics and overall performance of the device, medArtis AG believes that no significant differences exist between Synthacer® Calcium Salt Bone Void Filler and Syntricer® Calcium Salt Bone Void Filler and the predicate devices.

MedArtis AG believes the minor differences of the medArtis AG calcium salt bone void filler(s) and its predicate devices should not raise any concerns regarding the overall safety or effectiveness.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.



JUN 23 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Knut Hülse, Ph.D.
Regulatory Affairs
MedArtis AG
Gabriel-Max-Strasse 3
D-81545 München, Germany

Re: K041177

Trade Name: Synthacer® Calcium Salt Bone Void Filler and Syntricer® Calcium Bone
Void Filler

Regulation Number: 21 CFR 888.3045

Regulation Name: Resorbable calcium salt bone void filler device

Regulatory Class: II

Product Code: MQV

Dated: June 1, 2005

Received: June 3, 2005

Dear Dr. Hülse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

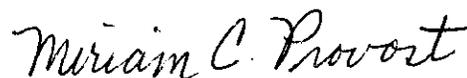
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041177

Device Name: Synthacer® Calcium Salt Bone Void Filler & Syntricer® Calcium Bone Void Filler

Indications for Use:

Synthacer® Calcium Salt Bone Void Filler is intended only for use as a bone void filler for voids or gaps in bone that are not intrinsic to the stability of the bony structure. Synthacer® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury.

Syntricer® Calcium Salt Bone Void Filler is intended only for use as a bone void filler for voids or gaps in bone that are not intrinsic to the stability of the bony structure. Syntricer® is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury.

Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter ___
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K041177