K121453 1/2

510(K) SUMMARY

FEB 0 5 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date of Prepare: Dec. 8, 2012

1. Submitter's Name: **AG DIGITAL Technology Corp.**

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Contact: Frank Chou / Manager

2. Device Name :

Trade Name: **A-GRIX TE Resorbable Bone Void Filler**

Common Name: **Bone Void Filler**

Classification name filler, bone void, calcium compound

3. DEVICE CLASS **A-GRIX TE Resorbable Bone Void Filler** has been classified as

Regulatory Class: II

Product Code: MQV

Panel : Orthopedic

Regulation Number: 21CFR 888.3045

4. Predicate Device: The predicate device is the

- **A-GRIX Resorbable Bone Void Filler (K091688)** marketed by **AG DIGITAL Technology Corp.**

5. Device Description: **The A-GRIX TE** Resorbable Bone Void Filler consists of 1 bottle of pre-measured surgical grade calcium salt mixture and 1 bottle of mixing solution. When mixed according to the direction, A-GRIX TE forms the biodegradable, biocompatible and radiopaque paste or putty for digitally applying directly or by dispensing into the defect site.

Then A-GRIX TE will harden in situ which acts as an osteoconductive scaffold and provides temporary intra-operative support to facilitate new bone growth. This product is supplied sterile for single patient use.

6. Intended Use:

A-GRIX TE Resorbable Bone Void Filler is indicated to fill bony void or gaps of the skeletal system (i.e., the extremities and pelvis) that are not intrinsic to the stability of the bone structure. These defects may be surgically created osseous defects created from traumatic injury to the bone. The bone void filler resorbs and is replaced with new bone during the healing process. **A-GRIX TE** Resorbable Bone Void Filler may be used at an infected site.

7. Performance Summary:

The device conforms to applicable standards includes ISO 10993 series : Biological evaluation of medical devices , ASTM F2224-03 : Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants & ANSVAAMI/ISO 11137 Sterilization of Health Care Products - Radiation Sterilization.

8. Conclusions:

The **A-GRIX TE Resorbable Bone Void Filler** has the same intended use and technological characteristics as the **A-GRIX Resorbable Bone Void Filler (K091688)** marketed by **AG DIGITAL Technology Corp.**. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **A-GRIX TE Resorbable Bone Void Filler** is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

AG Digital Technology Corporation
% Harvest Consulting Corporation (USA)
Ms. Jennifer Reich
Senior Consultant
2904 North Boldt Drive
Flagstaff, Arizona 86001

Letter dated: February 5, 2013

Re: K121453
Trade/Device Name: A-GRIX TE Resorbable Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 10, 2012
Received: December 14, 2012

Dear Ms. Reich:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K121453**

Device Name: **A-GRIX TE Resorbable Bone Void Filler**

Indications for Use:

A- GRIX TE Resorbable Bone Void Filler is indicated to fill bony void or gaps of the skeletal system (i.e., the extremities and pelvis) that are not intrinsic to the stability of the bone structure. These defects may be surgically created osseous defects created from traumatic injury to the bone. The bone void filler resorbs and is replaced with new bone during the healing process. A-GRIX TE Resorbable Bone Void Filler may be used at an infected site.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K121453