K103799

Section 5.0
510(k) Summary

Submitter Name:	ISTO Technologies, Inc.
Submitter Address:	1155 Olivette Executive Parkway, Suite 200 St. Louis, Missouri 63132
Contact Person:	Penny White Vice President, Regulatory Affairs and Quality Assurance
Direct Number:	314-262-8007
Company Main Number:	314-995-6049
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Date Prepared:	December 21, 2010
Device Trade Name:	InQu® Paste Mix Plus
Device Common Name:	Resorbable bone void filler
Classification Name:	Filler, bone void, calcium salt compound
Classification Number:	21 CFR 888.3045
Product Code:	MQV
Predicate Devices:	InQu®, ISTO Technologies, Inc., K063359 InQu®, ISTO Technologies, Inc., K071428 CarriGen Porous Bone Substitute, ETEX Corp., K093447
Statement of Intended Use:	InQu® is a resorbable bone void filler intended to fill bony gaps or voids that are not intrinsic to the stability of the bony structure. InQu® is intended for use as a bone graft substitute in the skeletal system (extremities and pelvis) and as a bone graft extender in the spine when combined with bone autograft. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.
Device Description, Summary of Technological Characteristics	InQu® Paste Mix Plus is intended for single patient use only. The device is a sterile, granular, synthetic bone void filler composed of poly (D,L-lactide-co-glycolide), hyaluronic acid and sodium carboxy-methylcellulose provided in powder form, added to improve handling characteristics. The two components are mixed at the time of use and combined with a fluid (e.g. saline or blood) to form a putty, which is easily placed into bony voids. It resorbs and is replaced with bone during the healing process.
Device Testing	ISTO performed a study comparing the dissolution rate and characteristics of the smaller granule size in the Paste Mix Plus to the granules in the predicate devices. The results show the two forms do not have significant differences.
Comparison to the Predicate Device	The new device is substantially equivalent to the predicate devices in terms of intended use, material composition and technological characteristics, as shown in the above testing.

AUG 29 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

ISTO Technologies, Incorporated
% Ms. Penny White
Vice President, Regulatory Affairs and Quality Assurance
1155 Olivette Executive Parkway, Suite 200
Saint Louis, Missouri 63132

AUG 29 2011

Re: K103799
Trade/Device Name: InQu® Paste Mix Plus
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: August 16, 2011
Received: August 17, 2011

Dear Ms. White:

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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K103799

Device Name: InQu® Paste Mix Plus

Indications for Use:

InQu® is a resorbable bone void filler intended to fill bony gaps or voids that are not intrinsic to the stability of the bony structure. InQu® is intended for use as a bone graft substitute in the skeletal system (extremities and pelvis). InQu® is indicated for use as a bone graft extender in the spine when combined with bone autograft. These defects may be surgically created osseous defects, or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

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

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103799