K082679 1/1

LAKI Hand Fixation System
510(k) Summary
June 2008

APR - 7 2009

I. Company: **Sintea Biotech, Inc.**
407 Lincoln Rd. Suite 10L
Miami Beach, FL 33139
(305) 673-6226

II. Proprietary Trade Name: LAKI Hand Fixation System

Regulation Number: 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener.

Product Code: JEC

III. Product Description
This 510(k) consists on the submission of an evolution of an external fixation device. The LAKI Hand Fixation System provides opportunity to patients to develop solid bone re-growth in cases of fractures, pseudo-arthrosis, and limb lengthening by use of modular elements, rods, and nuts. The LAKI utilizes a threaded rod bound to two semi modular elements with nuts which allows the former to be locked in the most suitable position for each specific case. Kirschner wires are also used for stabilization. All invasive components of the LAKI Hand Fixation System are made of 316L stainless steel. External locking connector components are all made of Ti6AL4V titanium alloy.

IV. Indications
The LAKI device is intended to be used for fixation of bone fractures of long bones in fingers. The LAKI device is a semi-invasive device intended to be attached through the skin so that a pulling force (traction) may be applied to the skeletal system.

V. Performance Data
Please see 510(k) submission for the SEM Modular External Stabilizer, K880282.

VI. Substantial Equivalence
Sintea Biotech, Inc. believes that the LAKI Hand Fixation System is substantially equivalent to the LIMA SEM Modular External Stabilizer (K880282) with respect to functional design, indications for use, and principles of operation, performance, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Sintea Biotech, Inc.
% Ms. Danielle Wernikowski
407 Lincoln Road, Suite 10L
Miami Beach, Florida 33139

Re: K082679
Trade/Device Name: LAKI Hand Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JEC
Dated: March 12, 2009
Received: March 12, 2009

Dear Ms. Wernikowski:

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.

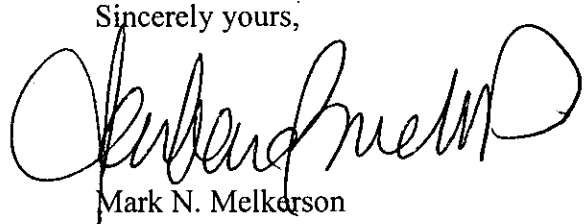
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
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): K082679

Device Name: LAKI Hand Fixation System

Indications for Use:

The LAKI device is intended to be used for fixation of bone fractures of long bones in fingers. The LAKI device is a semi-invasive device intended to be attached through the skin so that a pulling force (traction) may be applied to the skeletal system.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082679