K053638

1/2

FEB 9 2005

510(k) SUMMARY
MANI Needle and Suture Pack
MANI, Inc.

This 510(k) summary of safety and effectiveness for the MANI Needle and Suture Pack (Silk) is submitted in accordance with the requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	MANI, Inc.
Address:	743 Nakaakutsu Takanezawa-Machi Tochigi 329-1234 Japan (Headquarters)
Contact Person:	David J. Bloch Regulatory Counsel
Telephone:	(202) 414-9209 (telephone) (202) 414-9209 (fax)
Preparation Date:	January 2005
Device Trade Name:	MANI Needle and Suture Pack (Silk)
Common Name:	Guide Needle, Surgical; Non-Absorbable Suture, Silk.
Classification Name:	Guide Needle, Surgical; (see 21 C.F.R. § 878.4493) Non-Absorbable Suture, Silk (21 C.F.R. § 878.5030) Product Code: GAP
Predicate Devices:	Alcon Laboratories Needles and Sutures, 510(k) # 760158.
Device Description:	The MANI Needle & Suture Pack (Silk) consists of a stainless steel needle and silk suture, for use in short term soft tissue approximation, including use in ophthalmic surgery, but not for use in cardiovascular and neurological tissue.
Intended Use:	The MANI Needle & Suture Pack (Silk) is intended for use in short term soft tissue approximation, including use in

ophthalmic surgery, but not for use in cardiovascular and neurological tissue.

CONCLUSIONS: Based on the foregoing and other information in this application, MANI, Inc. believes that the MANI Needle & Suture Pack (Silk) is substantially equivalent to its claimed predicates under conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2006

MANI, Inc.
% ReedSmith
Mr. David J. Bloch, Esq.
1301 K. Street, NW
Suite 1100 – East Tower
Washington, District of Columbia 20005-3373

Re: K053638
Trade/Device Name: MANI Needle & Suture Pack (Silk)
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural nonabsorbable silk surgical suture
Regulatory Class: II
Product Code: GAP
Dated: April 24, 2006
Received: April 26, 2006

Dear Mr. Bloch:

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) 276-0115. 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/dsma/dsmamain.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

K053638

Indications for Use

510(k) Number (if known): _____

Device Name: MANI Needle & Suture Pack (Silk)

Indications For Use:

The MANI Needle & Suture Pack (Silk) is intended for use in short term soft tissue approximation, including use in ophthalmic surgery, but not for use in cardiovascular and neurological tissue.

Prescription Use X 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)

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

510(k) Number K053638