16. 510(k) Summary of Safety and Effectiveness

NOV - 9 2004

SUBMITTER:	SURGICHIP, Inc. 4398 Hickory Drive Palm Beach Gardens, FL 33418
CONTACT PERSON:	Bruce Waxman, M.D. President
DATE PREPARED:	September 1, 2004
CLASSIFICATION NAME:	Skin Marker
COMMON NAME:	Skin Marker
PROPRIETARY NAME:	SURGICHIP™ Tag
PREDICATE DEVICES:	Skin Marker (Sec. 878.4660)
DEVICE DESCRIPTION:	The SURGICHIP™ Tag smart label and procedure that uses Radio Frequency Identification technology to mark an anatomical site prior to surgery. It is designed to be used in addition to the usual safeguards so that the correct procedure is performed on the correct site and on the intended patient.
INTENDED USE:	The SURGICHIP Tag is intended to mark an anatomical site for surgery.

SUMMARY:

The SURGICHIP Tag is substantially equivalent to a Skin Marker, an Adhesive Surgical Site Marker, and a RFID Hospital Identification Wristband. These devices are identical with regard to their intended use. SURGICHIP Tag, the Skin Marker, and the Adhesive Surgical Site Marker differ in some degree in their technological characteristics but they all mark a surgical site prior to surgery and they act to provide another level of confirmation for the surgical team prior to operating on the patient. The SURGICHIP Tag and the RFID Hospital Identification Wristband use the identical technological characteristics to corroborate that the correct surgery will be performed on the correct patient and the correct body part by displaying patient and surgical procedure specific information.

Testing of the subject device demonstrated that the SURGICHIP Tag is an effective method of marking a surgical site prior to surgery and is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2004

Bruce Waxman, M.D.
President
SURGICHIP, Inc.
4398 Hickory Drive
Palm Beach Gardens, Florida 33418

Re: K042555
Trade/Device Name: SURGICHIP™ Tag Surgical Marker
Regulation Number: 21 CFR 878.4660
Regulation Name: Skin marker
Regulatory Class: I
Product Code: FZZ
Dated: October 28, 2004
Received: November 1, 2003

Dear Dr. Waxman:

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,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
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): KO42555

Device Name: SURGICHIP™ Tag Surgical Marker

Indications for Use:

The SURGICHIP Tag surgical marker is indicated to mark an anatomical site for surgery.

Prescription Use ___XXX___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K042555

(Posted November 13, 2003)