K033575

B|BRAUN

FEB - 9 2004

7. 0 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown PA 18109-9341

Contact:
Jennifer A. Kosoy, Senior Analyst, Regulatory Affairs
(610) 266-0500 ext. 2516

DEVICE NAME:

one.click™ needle

COMMON OR USUAL NAME:

Pen needle

DEVICE CLASSIFICATION:

Class II, per Code of Federal Regulations, Title 21 § 880.5570 Hypodermic Single Lumen Needle

PREDICATE DEVICE:

Owen Mumford, Inc. Unifine® Pentip® (K973899)

DESCRIPTION:

The one.click needle is a double-ended needle consisting of a tribeveled tip, hollow steel cannula, needle hub and needle shield. The one.click needle will be available as a 29 Gauge needle, with a patient-end needle length of 12 millimeters.

INTENDED USE:

The one.click needle is a sterile, single-packed, disposable hypodermic single lumen needle designed for use with a multidose pen injection device, the one.click auto-injector, for the subcutaneous injection of fluid drug products.

SUBSTANTIAL EQUIVALENCE:

The proposed one.click needle has the same materials, method of construction, and is similar in design to the Unifine® Pentip®, currently manufactured by B. Braun for Owen Mumford Inc. under the Premarket Notification K973899 (Unifine Pentip). The one.click needle differs from the Unifine Pentip in range of needle lengths, needle diameter, and color of needle shield. The needle gauge and length of the one.click needle is within the sizes cleared in the Unifine Pentip 510(k). The one.click needle is similar to the Unifine Pentip in indications for use, as noted in product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2004

Ms. Jennifer A. Kosoy
Senior Analyst, Regulatory Affairs
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allenstown, Pennsylvania 18109-9341

Re: K033575
Trade/Device Name: One.Click™ Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: November 12, 2003
Received: November 12, 2003

Dear Ms. Kosoy:

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 (301) 594-4618. 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,

for, Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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2.0 Indications for Use Statement

510(k) Number (if known): K033575

Device Name: one.click™ needle

Indications For Use:

The one.click needle is a sterile, single-packed, disposable hypodermic single lumen needle designed for use with a multidose pen injection device, the one.click auto-injector, for the subcutaneous injection of fluid drug products.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K033575