DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

Robert T. Handren, Jr., M.S.
President
Handren Associates, Incorporated
5818 Princess Caroline Place
Leesburg, Florida 34748

Re: K983367
Trade Name: QLICKSMART®
Regulatory Class: II
Product Code: MMK
Dated: September 23, 1998
Received: September 24, 1998

Dear Mr. Handren:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983367

Device Name: QLICKSMART®

Indications For Use:

1. "Permits the safe and simple removal of scalpel blades from most commonly used scalpel handles"

2. "Safely contains the blade immediately upon removal, eliminating the need for further handling prior to disposal"

3. "The counter allows the user to monitor its use to see when it is becoming full and will need changing"

4. "Scalpel handles compatible with the QLICKSMART® include:

Swann Morton Blade sizes 3, 4, 7 and 9
Lawton Blade sizes 3 and 4
Martin Blade sizes 3, 4 and 7
Smic Blade sizes 3 and 4
Aesculap Blade sizes 3, 3L, 4 and 7
Sayco Blade sizes 3, 4 and 5
Nopa Blade sizes 3 and 4
Lance Blade sizes 3 and 4
Conqueror Blade size 3
Pro-Med Blade sizes 3 and 4
Paragon Blade sizes 3 and 4
Feather Blade size 7
Rocket Blade size 5
Generic Blade size 4
ab stainless Blade size 4
LRI Blade size 4
Jakobi Blade Size 4"

5. "Scalpel handles known to be incompatible with the QLICKSMART® include:

Barron Handle
Beaver Type Handles
Disposable Handles."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____

(Optional Format 1-2-96)

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

510(k) Number _____