

3/8/99

K98 3105

9.0 Summary of Safety and Effectiveness

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA, 1990.

Submitted by: CCS Inc.
5 Oxford Street West, London, Ontario, Canada. N6H 1R1
Phone 519-672-1190 Fax 519-672-8557

Prepared by: CATCO:Competitive Advantage Tools Company
2288 Yorktown Circle, Mississauga, Ontario, Canada. L5M 5Y2
Phone 905-819-9425 Fax 905-819-9562
Steve Long, President

Date: August 31, 1998

Trade Name: CCS Computer Controlled Syringe (Model CCS-100)
CCS Cartridge Holder (Model CCS-100-01)

Classification: Class II. 21 CFR 872.6770

Predicate Device: The Wand (K961648)

Device Description: The CCS computer controlled syringe is a programmable electronic device that allows the injection of local anesthetics commercially available and packaged in cartridge form. The device consists of a programmable *control unit*, and a *handpiece* with switches that actuate the function of the device as programmed. Single use, replacement cartridge holders are available to facilitate universal injection technique.

Intended Use: Indicated for the injection of local anesthetics for infiltration and nerve block anesthesia administered prior to, or in conjunction with, dental procedures.

Sterility: The described devices are non-sterile.

Performance Data: Performance data is presented in the 510(k) submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 1999

Computer Controlled Syringe, Incorporated
C/O Mr. Steve Long
President
CATCO:Competitive Advantage Tools Company
2288 Yorktown Circle
Mississauga, Ontario, CANADA L5M5Y2

Re: K983105
Trade Name: CCS; Computer Controlled Syringe, Model
#CCS-100, CCS; Cartridge Holder, Model #CCS-100-01
Regulatory Class: II
Product Code: EJI
Dated: February 18, 1999
Received: February 22, 1999

Dear Mr. Long:

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 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.

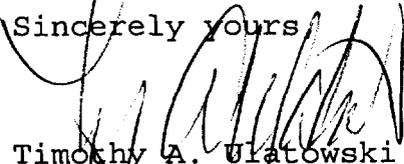
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

Page 2 - Mr. Long

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" (21 CFR 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/dsmamain.html>".

Sincerely yours



Timothy A. Wlatowski
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): K983105

Device Name: CCS

Indications For Use:

The CCS Computer Controlled Syringe is an electronic programmable device indicated for the injection of local anesthetics for infiltration and nerve block anesthesia administered prior to, or in conjunction with, dental procedures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runtz

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

510(k) Number K98 3105

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use