K964802

MAY 27 1997

Appendix V
Summary of Safety and Effectiveness Information

Section 510(k) Premarket Notification Summary of Safety and Effectiveness Information Cyberjet™ Local Anesthesia System	CYBERDENT, INC.

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Trade Name: Cyberjet™ Local Anesthesia System

Common Name(s): Local Anesthesia System for Intraosseous Injection

Classification Name(s):

1. Dental Injecting Needle
2. Handpiece, Direct Drive, AC-Powered
3. Injector, Jet, Mechanical-Powered

2. Establishment Name & Registration Number:

Name: CYBERDENT, INC.

Number: Pending

3. Classification:

1. **§ 872.4730 Dental injecting needle.** (a) Identification. A dental injecting needle is a slender, hollow metal device with a sharp point intended to be attached to a syringe to inject local anesthetics and other drugs. (b) Classification. Class I.

2. **§ 872.4200 Dental handpiece and accessories.** (a) Identification. A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. (b) Classification. Class I. [55 FR 48439, Nov. 20, 1990]

3. **§ 872.4475 Spring-powered jet injector.** (a) Identification. A spring-powered jet injector is a syringe device intended to administer a local anesthetic. The syringe is powered by a spring mechanism which provides the pressure to force the anesthetic out of the syringe. (b) Classification. Class II.

Product Code(s):

1. 76DZM
2. 76EKX
3. 76EGH

Device Class:

1. 76DZM - Class I
2. 76EKX - Class I
3. 76EGH - Class II

Classification Panel:

1. Dental Devices Panel
2. Dental Devices Panel
3. Dental Devices Panel

4. Applicant / Sponsor Name / Address:

CYBERDENT, INC.
354 Bel Marin Keys, Suite I
Novato, CA 94949
415.883.0484
415.883.3037 - fax

5. Contact Person:

Mr. Gin Wu, Ph.D.
CYBERDENT, INC.
354 Bel Marin Keys, Suite I
Novato, CA 94949
415.883.0484
415.883.3037 - fax

6. Equivalent / Predicate Device(s):

1. **Stabident System** - Intraosseous Local Anesthesia - K910446

7. Description of the Device:

Introduction. The **Cyberjet™** is a dental device intended for intraosseous injection of local anesthetics. Intraosseous injection of local anesthetics is a long-standing technique in dental anesthesia that was developed in the early 1900's and is still in common use in dental anesthesia today. Intraosseous injection requires the dentist to drill a small hole in the bone adjacent to the problem tooth. The dentist then uses a standard anesthesia needle and syringe to inject the local anesthetic solution into the previously drilled hole to numb the nerve of the tooth.

The **Cyberjet™** combines the dental drill and the injection needle into one device and performs both the drilling and injection functions with the same device. After an appropriate injection site has been identified, a topical anesthetic is applied to the gum, followed by a few minutes wait to allow the topical anesthetic to take effect.

The previously selected injection site is located and the dill motor and the injection motor are turned on. The tip of the drill/needle is placed on the overlying gum and pressure is applied. The drill/needle passes through the soft tissue and starts to perforate the cortical plate. After the penetration of the cortical plate, the drill motor is turned off by releasing the momentary-switch on the foot-pedal. Local anesthetic is continuously dispensed into the tissue during and after the drilling process through the Infuser. Use of the **Cyberjet™** will result in a simple one-step intraosseous injection for dental anesthesia.

The system includes 5 components:

1. A **Hollow Tubing Needle** referred to as a drill/needle or Infuser that serves as a drill as well as a hypodermic injection needle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1997

Cyberdent, Incorporated
C/O Mr. David W. Schlerf
Buckman Company, Incorporated
1000 Burnett Avenue, Suite 450
Concord, California 94520

Re: K964802
Trade Name: Cyberjet™ Local Anesthesia System
Regulatory Class: I
Product Code: DZM
Dated: February 26, 1997
Received: February 27, 1997

Dear Mr. Schlerf:

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.

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. 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): K964802

Device Name: CYBEJET LOCAL ANESTHESIA SYSTEM

Indications For Use:

1. Administration of intraosseous anesthesia for dental indications.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Susan Runner
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K964802

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)