

FEB

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510 (K) SUMMARY

K973996

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation, (ODE) HFZ-400  
Document Mail Center HFZ-401  
9200 Corporate Boulevard  
Rockville, MD 20850

**510 (k) Submission**

**Device Proprietary name:**

CLEARLINE® PLUS, dental waterline filter

**Device common name:**

Membrane filter with combined anti-retraction check valve

**Establishment Registration Number:**

3027751

**Class in which device has been put under Section 513:**

Class I: Predicate device was on interstate market prior to 1976. Other comparable devices have received 510 (k) clearance since the Device Amendment. SciTech's one day filter (K.930144) was given regulatory clearance on December 3, 1993. SciTech's anti-retraction check valve (K.960556) was given clearance on February 9, 1996. MLRB International, Inc. received clearance for a similar device (K.963548) on January 22, 1997.

**Action taken by party to register to comply with Section 514:** Not applicable.

**Proposed labels, labeling and advertisements, sufficient to describe the device, its intended use and directions for use:**

The device is not currently marketed for this application. No promotional materials have been finalized and packaging is not yet available; it will be forwarded for review, once finalized, and will be based on allowable claims.

**510 (k) Summary:**

See attached 510 (k) Summary of efficacy and safety data on separate numbered sheets (Summary pages 1-3).

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**Photographs of the Device:**

See attached print photograph of the device at Exhibit 1 (page 10). The device incorporates the membrane filter which has already been cleared for five working days of use (K.963548) together with the anti-retraction check valve (K.960556) attached on the outlet port by use of an adapter.

**Engineering Drawings of the device:**

The engineering drawings of the individual components of the device are attached as the following exhibits:

- Exhibit 2A - filter cartridge (page 11)
- Exhibit 2B - check valve (page 12)
- Exhibit 3C - adapter for check valve (page 13)

**Identification of the marketed device to which equivalence is claimed:**

- Filter - Dentapure cartridge (K.963548), MLRB International Inc.
- Clearline<sup>®</sup> cartridge (K.930144), SciTech Dental Inc.
- Checkvalve - BacStop<sup>™</sup> (K.960556), SciTech Dental Inc.

**Statement of Similarities and differences between CLEARLINE<sup>®</sup> PLUS and the predicate, marketed device:**

Clearline<sup>®</sup> Plus is a disposable microfiltration cartridge with approximately 10 sq. cms. of polyethersulfone membrane with 0.2 micron pores and a normally closed check valve at the exit port. The check valve has a silastic rubber membrane which operates with a cracking pressure of 1.5 psi. The predicate device (Dentapure) is a disposable micro filtration cartridge which contains the same area of filter membrane, the same type of housing and is made by the same manufacturer (Millipore Corporation). It has been FDA cleared for five working days of filtration use in dental unit water lines. Dentapure, however, is filled with an iodinated resin in the cartridge space, upstream of the filter membrane, so that any viral particles, which may be sucked back from a patient's mouth and pass through the pores of the membrane, are subject to the antiviral action of the iodine.

The iodine also leaches out of the iodinated resin reserve and enters the water stream, so that several parts per million of iodine are present in the water exiting from the device; this provides a decontaminating effect on any bacteria or viruses that are sucked back into the waterline down stream from the device. By comparison Clearline<sup>®</sup> Plus accomplishes this function by the use of a check valve on the exit. This normally closed valve prevents back

flow and thereby avoids contamination of the water line downstream of the device, throughout the five day working life of the unit. Both Clearline® Plus and Dentapure are designed to fit in the dental line close to the coupling point for the hand piece, air/water syringe and ultra-sonic scaler.

**Data to show consequences of modified device:**

Not applicable.

**Submitter's name and address:**

Simon Johnston  
SciTech Dental, Inc.  
562 First Avenue South, Suite 700  
Seattle, WA 98104  
FDA establishment registration number: 3027751  
Owner/Operator I.D. 9011186  
TEL # 800 524 6984 or 206 382 0880  
FAX # 206 382 0823

**Contact person, telephone #, fax #:**

Clive Defty  
TEL # 206 382 0880  
FAX # 206 382 0823

**Representative/consultant:**

Not applicable.

**Table of Contents:**

See cover sheet.

**Name and address of manufacturing and packaging facilities:**

SciTech Dental, Inc.  
562 First Avenue South, Suite 700  
Seattle, WA 98104  
FDA reg. #3027751

Millipore Corporation  
80 Ashby Road  
Bedford, MA 01730  
FDA reg. #2647612

Filter manufacturer

B. Braun Medical, Inc.  
824 Twelfth Avenue  
Bethlehem, PA 18018  
FDA reg. #2523676

Check Valve manufacturer,  
assembly and packaging

**Comparison Table of the new device to marketed devices:**

	<b>CLEARLINE® PLUS</b> In-line membrane filter and check valve	<b>DENTAPURE</b> In-line disposable membrane filter	<b>BACSTOP™</b> Anti-retraction Check Valve
<b>Intended use</b>	In-line control of bacterial contamination and water retraction in dental hoses	In-line control of bacterial contamin- ation and water retrac- tion in dental hoses	In-line control of water retraction in dental hoses
<b>Size-length</b>	9.0 cm	6.5 cm	2.4 cms
<b>Size-width</b>	1.5 cm	1.5 cm	1.3 cms
<b>Composition- Housing</b>	Ektar DN003 and Lexan polycarbonate	Ektar DN003	Lexan polycarbonate
<b>Filter membrane</b>	0.22 micron polyether- sulfone	0.22 micron poly- ethersulfone	N/A
<b>Vent membrane</b>	Polyvinylidene fluoride	Polyvinylidene fluoride	N/A
<b>Anti-retraction Component</b>	Silastic rubber disc	2.5 cc iodinated Ion exchange resin	Silastic rubber disc
<b>Replacement Schedule</b>	Weekly (five working days)	Weekly (five working days)	Daily
<b>Fittings-inlet</b>	Female luer	Female luer	Female luer
<b>Fittings-outlet</b>	Male luer	Male luer	Male luer
<b>Cracking pres- sure of check valve</b>	1.5 psi	N/A	1.5 psi
<b>Max. working pressure</b>	70 psi	70 psi	70 psi

**Action taken to comply with voluntary standards:**

Not applicable.

**Performance data on the device:**

Twelve Clearline® Plus devices were performance-tested for their potential utility as bacterial retention filters in dental waterlines by placement in-line in a standard (Proma Dental Equipment Co.) dental unit hose with luer mounts, close to the coupling connection for a handpiece, syringe or scaler. The unit was supplied with a water source through a "bottled water" or "clean water" delivery system, manufactured by Ampco Dental Co., pressurized to 35 psi with Nitrogen gas from a cylinder. The bottled water system was charged daily with a challenge bacterial suspension, containing ~100,000 cfu/mL of test organisms (*Serratia marcescens*). Approximately 1.5 liters of this suspension was passed through the Clearline® Plus each day for 5 days, over a period of about 8 hours. In between the test periods the units were left stagnant, just as they would be under normal working conditions, with the Clearline® Plus cartridges still in place.

The challenge suspension was delivered in two modes, so as to mimic the pulsatile flow usually associated with use of dental handpieces or syringes. In the first mode (Exhibit 3A), six sterile Clearline® Plus cartridges were each put in-line and tested with intermittent pulses of water flow of 20 seconds duration, with a period of stasis in between, so as to ensure that over the 8 hour test period between 1 and 1.5 liters of the bacterial suspension passed through the device during 50 operating cycles. Intermittent pulses were delivered with precision by use of a programmed microprocessor-controlled solenoid valve.

In the second mode (Exhibit 3B), delivery of the test volume was accomplished over the 8 hour period in a series of intermittent 3 second pulses and 250 operating cycles per day. At the end of each mimicked "working day" a 100 mL sample of the filtrate was collected through each Clearline® Plus into a sterile container and subjected to the Milliflex (Millipore Corporation), bacterial counting test system, so as to be able to detect contaminating *Serratia* with a high sensitivity (<1/100 mL of filtrate). In this way it was possible to assess the daily performance in terms of the bacterial retention efficacy and to define, over the course of the 5 days, what the total capacity would be.

The results are shown in the Exhibits for each of the two modes of delivery. In no instance was *Serratia* contamination of the filtrate detected even after passage of more than 8 liters of the test suspension, and over 1,000,000,000 cfu of bacteria over the course of the 5 day test period. These conditions represent extremes which are very unlikely to be faced as a routine in the dental operator, and the results justify the conclusion that, under normal working conditions, Clearline® Plus has sufficient retention capacity to ensure passage of filter sterilized water for at least 5 working days in the dental operator into the tubing downstream of the device.

In the initial installation of Clearline® Plus, the downstream tubing section is replaced with a sterile section, connecting the exit luer of the device to the coupler. This section of tubing is subject to contamination by organisms sucked back from the patient's mouth

unless protected by a check valve. BacStop™ (K.960556) disposable check valves have been shown to be effective in achieving this protection when used in conjunction with daily disposable Clearline® Microfiltration cartridges (K.930144). For the development of Clearline® Plus it was necessary to establish the performance capacity of this normally-closed check valve when used as an integral component part of the microfiltration/check valve device.

BacStop is a normally-closed backflow prevention check valve that consists of a flat silastic rubber disc valve in a housing, sealed by sonic welding, that provides for luer connection to in line fittings. The housing parts are made of clear Lexan 124 polycarbonate. It is used in infusion I/V sets to control backflow. When placed in line in dental water hoses, it opens only when sufficient pressure is applied, usually about 1.5 psi. When the pressure falls, the valve snaps closed and thus prevents any fluid from going back up the line.

BacStop was cleared for daily use as a disposable check valve for dental water lines (K#960556) and is the only FDA cleared device for this purpose. Clearance came after data was submitted to the FDA for this device. The data confirmed that after 250 on/off cycles representing a "worst case scenario" for the use pattern in a dental unit during one day's work, the check valve was able to completely prevent any suckback of either bacteria or viruses, when a negative pressure was applied upstream of the check valve. In order for the test to be more sensitive, no handpiece or air/water syringe was used. Pursuant to A.D.A/A.N.S.I. specification #47, promulgated by the American Dental Association, approximately 45 microlitres of retraction is allowed into a handpiece, because this is insufficient to reach the dental water lines upstream of the coupling. Accordingly, any retraction of less than this amount will not be drawn into the tubing, but will be retained within the instrument and sterilized by routine autoclaving.

A suspension of a marker bacterium, *Chromobacterium violaceum* (ATCC 553), was used to show that no organisms were able to get up into the tubing even when the tubing tip, six inches downstream of the valve, was inserted into a heavy suspension of this organism. The same conclusion was reached with a suspension of viruses. In these tests, less than 0.1 microliters would have been detected if there had been any passage into the six inch length of tubing (between the valve and the tip of the tubing) after applying the negative pressure upstream. This sensitivity was achieved by culturing the entire contents of the tubing, between the valve and the tip, after the test conditions had been applied.

In order to evaluate the potential for this valve to be useful for 5 days, as a component part of Clearline® Plus, the number of on/off cycles experienced by the valve was extended to 1,250 cycles over 5 consecutive 8 hour sessions, with stasis of flow in between, in conditions comparable to those described above for retention capacity testing of the Clearline® Plus filter membrane. The intention was to mimic a heavy use pattern of the valve for a working week (5 days) in a dental line. Over the course of the testing, approximately 5 liters of water passed through each of 6 Clearline® Plus devices (in which the BacStop™ valves are integrated), with a pressure of 35 psi, and a pulse length of 3 seconds each.

By daily testing, it was established that there was no failure of any single valve tested on days 1-4 after experiencing this use pattern. At the end of the fifth day of pulsing through

the 6 Clearline® Plus test devices, the *Chromobacterium* backflow test was again performed. Three valves of the units subjected to this “working week” of pulses showed zero bacteria on culturing the downstream tube contents, indicating that no backflow of the test suspension at all had occurred. The other three check valves showed that an average of 0.11 microliters of the suspension had been drawn into the tubing when tested at the end of the fifth day. As mentioned earlier, since no handpiece or syringe tip was used on the line, it would take approximately 45 microlitres of retraction for material to reach the dental water line upstream of the coupler. These results demonstrate, therefore, that there will be no contamination of the dental water line. This level of control of backflow is entirely compatible with our claim of utility of the check valve in Clearline®, even after experiencing 5 working days of on/off cycling. In the absence of the valve, the tubing yielded approximately 170,000 bacteria in a total volume of about 200 microliters, when the slight negative pressure (3-5 psia suction) was applied upstream of the Clearline® Plus.

The conclusions drawn constitute the claims we make for the Clearline® Plus device and its substantial equivalence to Dentapure: a) that, when placed in-line in dental unit waterlines, Clearline® Plus will provide filter sterilized water and prevent bacterial contaminants in the dental water system from entering the water flow downstream of the device for a period of five working days, when subjected to a pattern of on/off use typical of that experienced in a dental operatory; and b) that over this working period, the device will prevent backflow (or “suckback”) of patient-derived microorganisms into a dental line, even when there is negative pressure applied upstream.

These claims are equivalent to those for Dentapure (K 963548), where it is stated that the device will “commonly reduce bacterial levels to less than one cfu/milliliter” downstream of the filter, and that use of Dentapure will “reduce the amount of bacteria that would reach the patient from the dental water system”, and that, in addition, the device “reduces the chance of cross-contamination by introducing the germicide iodine into the water system, downstream of the filter.” Use of both devices requires that current recommendations on instrument sterilization be followed by the practitioner.

**Sterilization, Software and Hardware information:**

It is intended that the device will be marketed in a sterile packaging. The final attachment of the check valve, packaging and sterilization (ETO) will be done at the following facility:

B. Braun Medical, Inc.  
824 Twelfth Avenue  
Bethlehem, PA 18018  
FDA reg. #2523676

**Information requested in specific guidance documents:** Not applicable.

**Kit Certification Statement:** Not applicable.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 4 1998

Mr. Clive Defty  
President  
Scitech Dental, Incorporated  
562 1<sup>st</sup> Avenue South #700  
Seattle, Washington 98104

Re: K973996  
Trade Name: Clearline Plus, Dental Waterline Filter  
Regulatory Class: I  
Product Code: EIA  
Dated: December 30, 1997  
Received: January 5, 1998

Dear Mr. Defty:

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 (Pre-market 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 requirement, 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 pre-market notification submission does

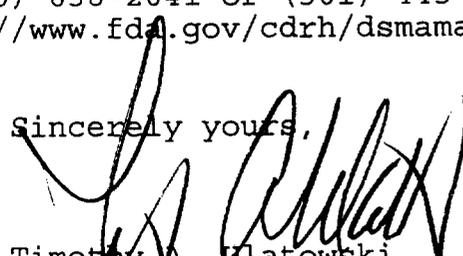
Page 2 - Mr. Defty

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) 594-4618. 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. Glatowski  
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): K973996

Device Name: CLEARLINE PLUS™ Dental waterline filter and check valve

**Indications For Use:**

CLEARLINE PLUS™ is a disposable, combined 0.22 micron filter and anti-retraction check valve for use in dental unit water lines. It is intended to be used, in line, as a means of controlling bacteriological contaminants in the dental water and preventing the retraction of orally contaminated fluids into the dental line. It is to be used for all patients and changed every week, or 5 working days.

CLEARLINE PLUS™ is to be installed within the last several inches of tubing, before the dental handpiece, air/water syringe or ultrasonic scaler. The filter comprises a 0.2 micron bacterial retentive membrane to reduce bacteriological contaminants in the dental water. The check valve opens only when sufficient pressure is applied (1.5 psi) and snaps closed when the pressure drops below this point, thereby sealing the line against any backflow. The device is inserted by connection to luer mounts placed permanently in line.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Susan Rumpf*

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

510(k) Number

K973996

Prescription Use   
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)