

JUN 25 1998

510 (k) SUMMARY

K982003

Submitted by:

Simon Johnston
SciTech Dental, Inc.
562 First Avenue South, Suite 700
Seattle, WA 98104
FDA Establishment Registration No. 3027751
Owner/Operator I. D. 9011186
TEL # 800 524 6984 or 206 382 0880
FAX # 206 382 9823

Date or preparation:

June 11, 1998

Trade Name of Device:

BACSTOP™ VALVE

Common Name of Device:

Weekly disposable in-line Anti-retraction check valve

Classification Name of Device:

Unknown

Legally Marketed Device to which BACSTOP™ VALVE is equivalent:

Clearline® Plus (K973996) and BacStop™ valve - daily (K960556) from SciTech Dental, Inc., 562 1st Avenue South, Suite 700, Seattle, WA 98104.

Description of the Device:

BacStop™ valve is a weekly disposable, normally closed anti-retraction check valve, consisting of a flat silastic rubber disc valve membrane in a housing made up of top and bottom parts, united by a sonically sealed joint. The two parts of the valve housing are made of clear Lexan 124R Polycarbonate, with the top (entry) port being in the form of a female Luer fitting, and the bottom (exit) port being in the form of a male Luer fitting, with locking collar. Total length of the device is 0.93 inches, width 0.5 inches. The nominal cracking (opening) pressure for the check-valve is 1.5 psi.

Intended use of the Device:

BacStop™ is intended for use in dental unit waterlines as a means of preventing the retraction of orally contaminated fluids into the coolant and irrigant water hoses. The unit is intended to be used for five working days (a weekly change), and is then to be discarded and replaced.

Technical Comparison to Predicate Device:

BacStop™ is a polycarbonate device manufactured for SciTech Dental Inc. by B. Braun Medical Inc. It is commonly used as a backflow prevention component in I/V Infusion sets, and is cleared for marketing for medical use under K790062. It is “normally closed”. When placed in-line in the dental water hose, it opens only under sufficient water pressure,, equivalent to 1.5 psi. The valve snaps closed and seals against backflow when the pressure drops below this point. The device is inserted by connection to luer mounts placed permanently in-line.

By comparison this BacStop™ valve for weekly use is the same device for both the BacStop™ valve for daily use and the valve found attached to the Clearline® Plus. 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. The BacStop™ valve for weekly use and the Clearline® Plus are designed to fit in the dental line close to the coupling point for the hand piece, air/water syringe and ultra-sonic scaler.

Non-clinical Performance Testing for Substantial Equivalence:

The substantial equivalence of the weekly BacStop™ valve is based upon the clearance of the Clearline® Plus. The Clearline® Plus units were tested for their capacity to continue to prevent backflow of bacterial contaminants after 5 consecutive days of use, during which no less than 1 liter of water passed through the device daily, in 8 hours, in 250 three second pulses. At the end of the 5 day working period, these 6 valves were tested for their capacity to prevent backflow of a suspension of bacterial when a slight negative “suckback” pressure was applied upstream of the device. The average amount of fluid withdrawn into the waterline was 0.05 microlitres, representing a 99.975% reduction in the amount of contamination drawn into a control apparatus, without functioning check valves, subjected to the same challenge. This amount of retraction would be retained in the instrument, and sterilized by autoclaving, and not enter the dental tubing.

Conclusions Drawn from the Non-clinical Laboratory Tests:

The conclusions drawn constitute the claim we make for the BacStop™ valve and its substantial equivalence to the Clearline® Plus and BacStop™ valve for daily use: that over this working period, the device will prevent backflow of patient-derived microorganisms, or “suckback” into a dental line, even when there is negative pressure applied upstream. Use of each device requires that current recommendations on instrument sterilization be followed by the practitioner.



JUN 25 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Clive M. Defty
President
SciTech Dental, Incorporated
562 First Avenue South, Suite #700
Seattle, Washington 98104

Re: K982009
Trade Name: One Week BACSTOP™ Dental Anti-Retraction
Check Valve
Regulatory Class: I
Product Code: EIA
Dated: March 24, 1998
Received: April 2, 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 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

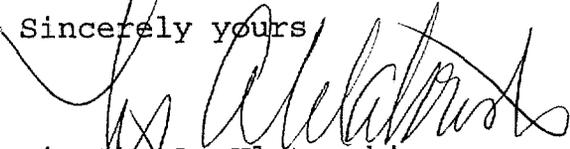
Page 2 - Mr. Defty

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) 638-2044 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): K982009

Device Name: BACSTOP™ Dental Waterline Anti-retraction Valve

Indications For Use:

The BACSTOP™ dental waterline Anti-retraction valve is normally closed disposable valve, which is replaced every week, or 5 working days. It is intended to be used in-line on dental unit water lines as a means of preventing the retraction of orally contaminated fluids into the coolant and irrigant water hoses. It is to be used for all patients.

BACSTOP™ is to be installed within the last several inches of tubing, before the dental handpiece, air/water syringe or ultra sonic scaler. It opens only under sufficient pressure (equivalent to 1.5 psi) and snaps closed and seals against backflow when the pressure drops below this point. 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)

Gerald Shipper

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982009

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)