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K963548



"510 (K) SUMMARY"
[As required by 807.92(c)]

Submitter: MRLB INTERNATIONAL, INC.
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Contact Person: Rex Hammarback, President

Date: August 27, 1996

Trade Name: DentaPure™ Cartridge

Common Name: Inline Water Filter

Classification Name: Accessory for "Unit, Dental Operative" per CFR 872.6640)
Class I.

Equivalent Device: Clearline™ Cartridge, (K930144)
Manufactured by:
SciTech Dental
562 First Avenue South, Suite 700
Seattle, Washington 98104
[per 807.92(a) (3)]

**Device Description
and Intended Use:**

The DentaPure™ Cartridge is an in-line filter assembly incorporating iodinated resin and a .22 micron filter. The filter is connected within 5" of the connection to the handpiece. This is illustrated in Figure 1.

A schematic of the cartridge is shown in Figure 2. It consists of a membrane type in-line filter with the outer chamber filled with an iodinated ion exchange resin that imparts 2-4 ppm of iodine

into the water as it flows through. The resin is registered with EPA. The filter portion is of a sufficiently small porosity to be bacterially retentive, and would thereby reduce the amount of bacteria that would reach the patient from the dental water system. The iodine that is released reduces the chance of cross contamination by introducing the germicide, iodine, into the water system downstream of the filter.

The DentaPure™ Cartridge is a disposable unit, retrofittable to all modern dental operatory units. The filter is installed in each dynamic instrument water tubing with quick connect fittings for ease of changing on a weekly basis.

The instructions for use of the DentaPure™ Cartridge require that the dental instruments be sterilized in conformity with current recommendations for sterilization and flushing. When used in conjunction with these normal practices, the DentaPure™ Cartridges commonly reduce bacteria levels to less than 1 cfu/ml. Current recommendations of the ADA recommend having less than 200 cfu/ml in dental unit water lines, so this device exceeds those recommendations.

Performance Data: Two tests have been conducted to show the efficacy of the DentaPure™ Cartridge and its substantial equivalence to the Clearline™ filter. Tests of the effectiveness of the iodine residual in cross contamination were conducted. Results showed an iodine residual in the tubing of .5 ppm in the first 5 ml, and less than 1 cfu/ml. Samples of the first 5 ml taken the next day showed little or no recontamination after 43 days.

The second set of tests to show equivalence and effectiveness were performed in a dental office, under actual conditions. Tests showed that inclusion of a 0.45 micron filter in conjunction with iodinated resin reduced the number of colony forming units from 10⁷cfu/100ml to less than 10cfu/100ml.

**Comparative
Technological
Characteristics:**

<u>Parameter</u>	<u>DentaPure™</u>	<u>Clearline™</u>
Filter Type	In-line Disposable	In-line Disposable

<u>Parameter</u>	<u>DentaPure™</u>	<u>Clearline™</u>
Installation Fittings	Luer-loc	Luer-loc
Components	Membrane Filter 0.22 micron Column Type 10.0cm ² Area 2.5cc Iodinated Ion Exchange Resin	Membrane Filter 0.22 micron Disc Type 4.2cm ² Area Chlorhexidine overnight soak
Maintenance	Weekly Change	Daily Change, connecting tubing between dynamic instrument and filter requires an overnight soak in Chlorhexidine.
Air-Lock Potential	Vented	Non-vented
Pressure Rating	70 PSI	75 PSI
Dimensions	1.5cm Diameter 4.5cm Length	2.8cm Diameter 2.3cm Length
Biosafe	USP Class VI	USP Class VI