

OCT 15 1998

Waggoner Product Development

7517 White Castle Ln

Plano, TX 75025

(972) 618-6090

Fax: (972) 491-1324

K981565

PREMARKET NOTIFICATION

510(k) SUMMARY

SAFETY AND EFFECTIVNESS

In response to the requirements addressed under section 513 (I)(3)(A) of the Act, I am enclosing a summary of the safety and effectiveness information upon which SUBSTANTIAL EQUIVALENCE determination is based.

CONTACT PERSON

Mark B. Waggoner, D.D.S.

President

Waggoner Product Development

7517 White Castle Ln.

Plano, TX 75025

(972) 618-6090

Fax: (972) 491-1324

CLASSIFICATION NAME: Dental Operative Unit and Accessories
(per 21 CFR section 872.6640)

COMMON NAME: Dental Operative Unit Waterline Disinfectant

PROPRIATORY NAME: BioClear Concentrate
Dental Operative Unit Waterline Disinfectant

CLASS: 1

12

SUBSTANTIAL EQUIVALENCE

BioClear Concentrate is similar in its intended use and mode of action to the **Dentosept P** disinfectant, legally marketed by both Pelton & Crane Company, Charlotte, N.C. with their Spirit 1/ 2, K962071 and Siemens Company, Germany, with their Sirona Water Purification Unit, K901672.

However, we feel that **BioClear Concentrate** is superior to **Dentosept P**, relative to its technological characteristics, its clinical performance and its safety.

DESCRIPTION OF DEVICE

The **BioClear Concentrate** is intended to be added to an independent water supply system reservoir bottle and would act as a constantly present disinfectant agent in the dental operative unit. It has been found to aid in the control of the microbial population in dental unit waterlines. A number of independent water systems can be purchased separately and retrofitted to a pre-existing dental operative unit or can easily be found included on a large number of newer dental operative units and are often referred to as a "clean water" systems. The **BioClear Concentrate** is composed of 16% Citric Acid, U.S.P./ F.C.C. as the only active ingredient. Other GRAS chemicals, 14.3% glucose F.C.C. , 0.8% Aspartame F.C.C., and 0.25% Sodium Benzoate F.C.C. (which only acts as a preservative for the concentrate), and 0.008% FD & C Blue #1. The artificial and natural sweeteners are added only to offer an agreeable flavor. The blue color is added to ensure the **BioClear Concentrate** has, in fact, been added to the tap water. The **BioClear Concentrate** would be mixed with tap water in a ratio of 7 ml/ 500 ml +/- 0.5ml to produce a final concentration of 0.224% citric acid, and would be changed daily. The dental operative unit should be purged/ flushed for 15 seconds every morning for the first 3 weeks. After this period of time, although recommended, it makes virtually no difference. All of these chemicals are Generally Recognized as Safe (GRAS) as per the FDA.

INTENDED USE OF DEVICE

Like Dentosept P, BioClear Concentrate is a dental operative unit waterline disinfectant. Both products are diluted (BioClear = 71.4water/1 BioClear and Dentosept P = 100 water/1 Dentosept P) in tap water (Dentosept P requires naturally or artificially softened water). This diluted mixture of either disinfectant is placed in an independent water reservoir system which supplies the dental operative unit. Thus, both disinfectants are constantly present in the waterlines and in the water delivered to the patient. Both disinfectants have been shown, in limited clinical and laboratory studies, to destroy the viability of the waterline bacterial biofilms tested (Dentosept P must not be diluted to accomplish this endpoint). Both of these disinfectants have also been shown, in clinical and laboratory studies, to kill several typical water borne bacteria (Dentosept P, in its diluted form is minimally effective against *Pseudomonas*). Dentosept P requires periodic "sanitizing treatment cycles". BioClear Concentrate, properly diluted (even in hard water) does not require special treatment cycles and can be left stagnant for one month without a loss of effectiveness.

TECHNOLOGICAL CHARACTERISTICS

Both properly diluted BioClear Concentrate and Dentosept P have been shown, in both limited clinical and laboratory studies, to destroy the viability of waterline bacterial biofilms tested. Dentosept P must be applied full strength to the dental operative unit waterlines for 24 hours, as a "sanitizing treatment cycle", to be effective. In testing, BioClear Concentrate was shown to destroy the viability of mature biofilms, at its diluted concentration, in 7 days of constant contact. BioClear has been further shown, in a laboratory study and a dental school clinical study, to eliminate all the biofilm matrix from the tubing samples examined by scanning electron microscopy, of a well established biofilm, with disruption seen as early as one week. Because of documented re-contamination with diluted Dentosept P, this 24 hour sanitizing treatment cycle must be repeated periodically throughout the year relative to bacterial testing results.

BioClear's superiority also relates to its ability to produce 7 log reductions in all planktonic bacteria as well as biofilm bacteria tested (both ATCC and wild type) when tested at only 89% of its recommended concentration. The

time kill capabilities of BioClear are most keenly exemplified by its ability for very rapid kill (10 minute, mean 5 log reduction) of the ATCC *Pseudomonas aeruginosa*, ATCC *Escherichia coli*, and ATCC *Klebsiella pneumoniae*. Variations in rate of kill were linked to the free chlorine levels found in the tap water. Kill rates for *Staphylococcus aureus* were 1 hour. This relates to BioClear's mechanism of action. Gram negative bacteria represent the vast majority of water originated bacteria.

Dentosept P's potential for biofilm regrowth relates to its inability to effectively kill Gram negative bacteria in time-kill experiments. Particularly alarming was the continued growth, after 72 hours in contact with the diluted Dentosept P, of *Pseudomonas*. This information is found in Attachment G: Predicate Device Information.

In a dental school clinical study, dental units utilizing properly diluted BioClear Concentrate were shown to have no bacterial growth detectable after being left stagnant for 4 weeks. This attribute allows the dentist to return to work after a vacation, and begin their practice immediately. BioClear Concentrate, after being utilized for at least 2 weeks, appears to offer the dental operative unit waterlines a bacteriostatic potential for up to 3 week into the future. This means that if a practitioner runs out of BioClear Concentrate for a week or two, their waterlines have been shown to still inhibit bacterial growth. If they utilize sterile water, they have been shown to deliver no bacteria, and if they utilize tap water, they have been shown to deliver water with contamination levels at the same or one log higher levels. This offers a "safety net" to the practitioner and patient should this occur. If Dentosept P treated water is left stagnant in the dental unit waterlines for a week, the dental unit waterlines must have a 24 hour sanitizing treatment cycle performed to bring the bacterial levels under control.

At a pH of 1.42, the BioClear Concentrate is bacteriocidal, and yeast-cidal. Some molds, like *Aspergillus niger* which can produce citric acid, are resistant to very low pH levels. Thus, sodium benzoate (a GRAS chemical which is utilized in the beverage industry to inhibit molds and yeasts) has been added at a percentage of 0.25% to eliminate the mold contamination potential (this is 7 times greater than the appropriate mycostatic dose at this pH). Repeated mold kill was seen at only 0.1%.

MECHANISM OF ACTION

The active agent in BioClear Concentrate is Citric Acid, while the active agents in Dentosept P are hydrogen peroxide and elemental silver. Citric acid functions as a chelator of divalent ions like Mg^{++} and Ca^{++} which bind certain cell wall constituents to the cell wall of Gram negative bacteria. Once the cell wall is compromised, it allows for easy ingress of hypochlorous acid and citric acid as well as allowing for osmotic disruption of the bacterial cell wall and membrane. The second mechanism involves the disruption of bacterial cellular function by chelating out essential ions for enzymatic function. The third mechanism is that of an acid. Citric acid's last pKa is 3.1, at which point $\frac{1}{2}$ of the citric acid is in its associated form. Properly diluted BioClear Concentrate has a pH of around 2.82. It is well accepted that an acid, in its associated form, can penetrate the cell wall and membrane and kill the bacteria. The final mechanism relates to the free chlorine found in tap water. Below a pH of 4.1, almost 100% of the free chlorine present will be in the hypochlorous acid form, which is 80 times more germicidal than the hypochlorite ion form. Citric acid was found to be effective with water hardness levels up to 400 ppm $CaCO_3$ and free chlorine levels as low as 0.0 ppm.

BioClear concentrate treated dental operative units also appear to possess a bacteriostatic potential into the future, even when only non-treated tap water is present, for up to 3 weeks. The bacteriostatic potential that citric acid offers to dental unit waterlines appears to be related to its binding to the tubing lumen.

Dentosept P utilizes hydrogen peroxide and elemental silver as its active agents. The literature states that hydrogen peroxide functions primarily by the production of hydroxyl radicals, which brings about oxidation of critical systems. Further studies have shown that hydrogen peroxide's effects are 80% reversed by 10mM of Mg^{++} , especially when the percentage of hydrogen peroxide is below 0.1%. Diluted Dentosept P has only 0.0141% hydrogen peroxide. This could be why soft water is required when using Dentosept P. Elemental silver is apparently a bacteriostatic agent and not truly a bacteriocidal agent.

SAFETY

BioClear is made from the active ingredient, Citric Acid, which is a "Generally Recognized as Safe" chemical by the FDA. To this is added other food grade GRAS chemicals like sucrose, aspartame, FD & C Blue #1 and sodium benzoate (at a final diluted concentration of only 0.0035%). The final diluted citric acid concentration is only 0.224%, which is slightly more concentrated than 7-up® (0.144%) and much less concentrated than lemonade (1.0 -1.1%).

Metal analysis of the treated water showed that no trace metals were found to reach levels which would pose a health hazard or an equipment destruction hazard. For the first week, Zinc levels were higher (0.750 mg/ 0.522 mg in the overnight 16ml draw) but these levels dropped to non-detectable levels on the third and fifth week because the surface atoms had been oxidized/ chelated out. Trace metals were found to reach their highest levels (still considered to be non-detectable) after being left stagnant overnight. Flushing the lines for about 15- 30 seconds was found to reduce the trace metals to levels below the source water content for the first 3 weeks. After this three week period, the flushing cycles appears to offer virtually no difference. Dental plastics and rubbers are resistant to high concentrations of citric acid.

Dentosept P is made from hydrogen peroxide diluted to 0.0141%, and elemental silver, diluted to 0.25 mg/liter (0.25 ppm). Although the hydrogen peroxide is probably safe in its diluted form, elemental silver raises questions. Only 5 rats were fed Dentosept P for one week for the toxic effect study. No long term heavy metal analysis was performed, and no study was performed relative to oral tattooing, argyria, on dental patients.

SUMMARY

Because of its intended use, as a dental waterline disinfectant agent, and its mode of action, as an agent constantly present in the dental operative unit waterlines, we feel that BioClear Concentrate is substantially equivalent to Dentosept P. We also feel that due to the technological characteristics, mechanism of action and well documented safety, BioClear Concentrate is substantially equivalent or an improvement over the comparative legally marketed Dentosept P.



OCT 15 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mark B. Waggoner, B.S., D.D.S.
Waggoner Product Development
7517 White Castle Lane
Plano, Texas 75025

Re: K981565
Trade Name: BioClear Concentrate
Regulatory Class: I
Product Code: EIA
Dated: July 21, 1998
Received: July 20, 1998

Dear Dr. Waggoner:

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 legally marketed predicate 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.

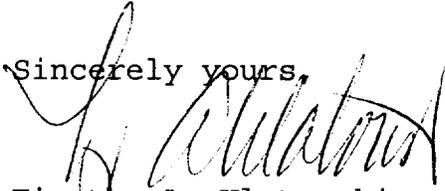
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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 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" (21CFR 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/dsma/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

