April 1, 2002

Mr. Garry Hollar
Director, Regulatory Affairs/Quality Assurance
Discus Dental. Inc.
8550 Higuera Street
Culver City, CA 90232

Review of *Zoom™* Chairside Whitening System

Dear Mr. Hollar,

At your request, we have reviewed the *Zoom™* Chairside Whitening System, and found the following:

The *Zoom™* Chairside Whitening System consists of a proprietary whitening gel and an Ultraviolet radiation emitting light source. The whitening gel consists of a two-part system of a hydrogen peroxide gel and an activator. The active ingredient, hydrogen peroxide, can be an irritant to tissues. To prevent such irritation, a dental dam resin (Liquidam™) is applied to all exposed gingival tissue. Cotton rolls and 2x2 inch gauze squares are used to cover all exposed tissues in the oral cavity and the upper/lower lips. The lips are covered with a sun protection factor (SPF) 35 sunscreen, containing UVA absorbers to further aid in protection against UV radiation. A facial bib is used over the cheek retractor to protect the tissue surrounding the mouth. The dentist, dental technician and patient wear appropriate protective eyewear for ultraviolet filtration.

The light source contains a short-arc metal halide lamp mounted in a protective housing. The emitted radiation is filtered by a 3mm thick KG-3 Infrared (IR) filter plus a 3mm Kopp-52 Ultraviolet (UVB/UVC) filter. The emitted radiation is projected through an aperture 0.75 by 2.15 inches, located at the end of the lamp housing. The distance to the patient's teeth is approximately 1.50 inches. This produces a radiation pattern to the teeth only, not to the surrounding tissues.

The optical emission at the working distance of 1.50 inches has been appropriately measured[1]. The following irradiances were measured:

UVC (250-290 nm) 1.96×10^{-8} W/cm^2
UVB (290-320 nm) 1.01×10^{-8} W/cm^2
UVA2 (320-340 nm) 7.64×10^{-7} W/cm^2
UVA1 (340-400 nm) 4.41×10^{2} W/cm^2

The biologic effectiveness of the amounts of UVC, UVB and UVA2 emitted by the light source are insignificant for any tissue damage. The UVA1 dose in a 20-minute period amounts to 53 Joules/cm^2.

UVA1 therapy for human disease, namely Atopic Dermatitis[2, 3] and Localized Scleroderma[4] and Cutaneous T Cell Lymphoma[5] has been used for a number of years. The UVA1 doses for therapy have been 130 Joules/cm^2 repeated to doses of more than 3000 Joules/cm^2 over several weeks. It appears that the minimal Erythema Dose for human skin is near 120 to 300 Joules/cm^2. (Personal communication from Professor Bernard Ortel, Department of Dermatology, Wellman Laboratory for Photobiology, Harvard University)

While UVA has been shown to be photocarcinogenic for the skin of albino hairless mice, a most recent Action Spectrum for cutaneous photocarcinogenesis[6] shows that UVA1 radiation is at least 3.94×10^{-4} times less effective than UVB. Furthermore, to produce skin cancer, albino hairless mice have to be irradiated for at least 100 Days (the equivalent of 10 human years).

A number of years ago, Parrish and Urbach[7] irradiated oral mucosa with total UVA and found that the mucosa was less sensitive than the skin. Doses of 40-50 Joules/cm^2 had no effect on the oral mucosa. Dr. Urbach has also had occasion to measure the transmission of UVA through extracted teeth (one incisor and one molar, cut in half to expose the pulp cavity) and was able to show that the transmittance to the pulp chamber was less than 1% of the externally applied radiation.

Finally, we have reviewed your suggested Chairside Whitening clinical study protocol. We believe that the risks to the patients and the dentist have been adequately minimized. We do want to support the exclusion of patients who have taken any photosensitizing agent such as antibiotics (a list is available from FDA), those suffering from Porphyria or other light sensitive conditions.

It certainly appears that with the use of recommended precautions, protective barriers, approved eyewear, and the lack of any stray radiation from the light source, the risk to dentists, dental technicians and patients is minimal.

Summary: The *Zoom™* Chairside Whitening System can be considered safe for the dentist, dental technician and patient. The amount of Ultraviolet Radiation emitted from the light source should, under the prescribed use conditions, cause no injury. Since all the radiation is delivered in one day, there is no likelihood of any skin cancer production.

Respectfully submitted,

Frederick Urbach MD, Dr.Med(hc) FACP
Emeritus Professor of Dermatology
Formerly Director, Center for Photobiology,
Skin and Cancer Hospital of Philadelphia

Robert M, Sayre, Ph.D.
President, Rapid Precision Testing Labs
Cordova, TN

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