SUMMARY OF SAFEY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name	Photodynamic Therapy Light
Device Trade Name	CureLight Broadband (Model CureLight 01)
Applicant's Name and Address	PhotoCure ASA Hoffsveien 49 N-0377 Oslo Norway
U.S. Representative	Dr. William A. Clementi Clementi & Associates 919 Conestoga Road Rosemont, Pennsylvania 19010
Date of Panel Recommendation	None
Premarket Approval Application Number	P010061
Date of Notice of Approval to Applicant	July 28, 2004

II. INDICATIONS FOR USE

The CureLight Broadband (Model CureLight 01) is indicated for use in combination with **TRADENAME** cream for treating non-hyperkeratotic actinic keratoses of the face and scalp in immunocompetent patients when used in conjunction with lesion preparation (debridement using a sharp dermal curette) in the physician's office when other therapies are unacceptable or considered medically less appropriate.

III. DEVICE DESCRIPTION

The CureLight Broadband lamp uses a halogen light source with appropriate band pass filters and has an adjustable light diameter of 30 to 55 mm. The lamp has been designed to deliver a stable and uniform distribution of red light in the range of 570 to 670 nm with a peak intensity of approximately 636 nm and provides a recommended dose of 75 J/cm^2.

This light distribution is designed to provide efficient tissue penetration into the target site as well as containing wavelengths that are preferentially absorbed by the target photosensitive compound.

IV. ALTERNATIVE PRACTICES AND PROCEDURES

Actinic keratoses are premalignant skin lesions that occur mainly in the sun-exposed areas such as the face, scalp, and backs of the hands. The lesions are skin colored or reddish brown, usually 3 to 10 mm in diameter, with dry, rough, adherent scales. Current therapy for actinic keratoses consists of cryosurgery, curettage, or topical application of 5-fluorouracil (5-FU).

V. MARKETING HISTORY

The CureLight Broadband (Model CureLight 01) has not been commercially distributed.

VI. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

For a list of adverse events observed in the clinical studies, please refer to the TRADENAME cream labeling. Although no adverse events have been reported for the use of, or operation of the CureLight Broadband (Model CureLight 01) lamp, there are potential adverse events that could be associated with either excess or too little light delivery. Too little light delivery could result in under treatment resulting in little or no therapeutic benefit to the patient. Over exposure, too much light, could result in thermal damage to the skin resulting in skin burns or excessive tissue necrosis.

VII. SUMMARY OF PRECLINICAL STUDIES

Three toxicity studies were performed in rats and minipigs to assess the tolerance of topically applied cream followed by photoactivation. The intent of these studies was to determine if use of TRADENAME cream plus light would induce systemic toxicity such as liver, kidney, heart failure or even death. The studies using rats treated 50 female and 50 male rats in both the single dose and repeat dose studies. Drug dose applied to the skin as well as light activation dose include dose levels equal to and greater than the planned clinical use doses. Animals were sacrificed at various times post treatment as well as being allowed to survive until complete wound healing. There was no evidence of any systemic toxicity in any animal although there were the expected dermal changes such as erythema, crusting, escar formation, and scab formation. All of the dermal effects did eventually heal as would be expected for such a dermal photodynamic therapy. The minipig study enrolled 8 male and 8 female minipigs and was limited to a single light dose and a single drug dose. This study compared the effects of drug alone versus drug plus photoactivation. The drug dose and light dose used were those used in the clinical study. Again there was not evidence of systemic toxicity but there were the expected dermal changes of erythema, escar, and scab formation. Application of drug alone produces a mild erythema that healed within a few days.

No pre-clinical studies were performed to evaluate light alone safety. The dose of light required for activation of TRADENAME cream is in the range of 50-200 mW/cm^2. This range of light exposure has been reported in the literature for several years as light exposure level that by itself has no effect on tissue including being of a level that does not induce even thermal effects.

VIII. SUMMARY OF CLINICAL STUDIES

The results of the clinical studies for the CureLight Broadband (Model CureLight 01) lamp in photodynamic therapy of face and scalp non-hyperkeratotic actinic keratoses are presented in PhotoCure's NDA 21-415. A summary of this data is contained in the attached labeling for TRADENAME cream.

IX. CONCLUSIONS DRAWN FROM STUDIES

The animal studies together with the clinical investigation reported in NDA 21-415 provide valid scientific evidence and provide reasonable assurance that the CureLight Broadband (Model CureLight 01) lamp is safe and effective for delivery of the required activation light for use with TRADENAME cream for the specified indication for use when used in accordance with the labeling.

X. PANEL RECOMMENDATION

The combination product was not referred to a Center for Devices and Radiological Health (CDRH) nor a Center for Drug Evaluation and Research (CDER) Advisory Panel for review and recommendation because the information substantially duplicates information previously reviewed by appropriate Advisory Panels.

XI. CDRH DECISION

CDRH concurred with CDER that the data presented in NDA 21-415 did demonstrate that the combination product using the PhotoCure ASA CureLight Broadband (Model CureLight 01) lamp with TRADENAME cream is safe and effective for the proposed indication for use and CDRH issued an approval order on July 28, 2004.

The device manufacturing facilities were inspected on May 15, 2002 and were found to be in compliance with the Quality System Regulation (21 CFR 820).

XII. APPROVAL SPECIFICATIONS

Information on the use of the CureLight Broadband (Model CureLight 01) lamp can be found in the Lamp Operator Manual. Instructions for use for the CureLight Broadband (Model CureLight 01) lamp with TRADENAME cream can be found in the package insert for TRADENAME cream. Postapproval requirements and restrictions can be found in the approval order.