

K063704

**FDA 510K Summary of Safety and Effectiveness for
BriteWhite Teeth Whitening System Professional**

1. General Information

Submitter: BEKS Incorporate
401 14th Avenue NE Unit #2
Jasper, AL 35501
888-582-3650
205-384-3940 Fax

FEB 20 2007

Contact Person: Jill Creasy
JC Consulting
694 Bluff St. #104
Carol Stream, IL 60188
630-480-0476
jcconsulting@comcast.net

Summary Preparation Date: December 3, 2006

2. Device Name

Proprietary Name: BriteWhite Teeth Whitening System (Professional)

Classification Name: Light source for bleaching teeth (21 CFR 872.6475).

3. Predicate Device

The BriteWhite Teeth Whitening System Professional is substantially equivalent in respect to the intended use, design and method of operation to numerous cleared devices, including; the South Beach Smile Light Whitening System (K042153), QuickSmile (K052040).

4. Device Description

The BriteWhite Teeth Whitening System device that utilizes Light Emitting Diodes to provide a tooth whitening system, the whitening light source is a mouth piece which is placed inside the mouth, using barrier sleeves, which emits a biologically safe and effective level of blue visible light. The general wavelength for the mouth piece is 400 nanometer spectrums to provide a selected wavelength which activates the whitening gel to bleach the teeth without the aide of heat. To ensure user safety when operating the light, the system has a built in feature to eliminate any risk for the end user and professional. The light automatically shuts off after a specified period of time. Secondly, the light source in placed inside the mouth, so there is no need for safety glasses for the patient and professional. No contact with the eyes is in this area of treatment and prevents penetrations of blue wavelength and protects the vision of the patient and professional.

5. Indications for Use:

1. The BriteWhite Teeth Whitening System is intended to emit light in the 400 nanometer spectrums to provide a light source for bleaching of teeth.

6. Technical Characteristics

The BriteWhite Teeth Whitening System and the aforementioned predicate devices are the light source for bleaching teeth as defined in 21 CFR 898.6475.

The BriteWhite Teeth Whitening System is an economical tooth whitening light which in conjunction with the whitening gel and tooth whitening preconditioning mouth wash provides a light source for bleaching the teeth. The BriteWhite Teeth Whitening System has similar intended use and technological characteristics to the predicate devices. The primary difference is the BriteWhite Teeth Whitening System uses an inside the mouth, hand piece.

7. Conclusions

The BEKS Inc. BriteWhite Teeth Whitening System has the same intended use, with similar functional and performance characteristics. The BEKS Inc. BriteWhite Teeth Whitening System performs as intended and does not raise any new safety or efficacy issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BEKS Incorporated
C/O Ms. Jill Creasy
JC Consulting
694 Bluff Street, #104
Carol Stream, Illinois 60188

FEB 20 2007

Re: K063704

Trade/Device Name: BriteWhite Teeth Whitening System
Regulation Number: 21 CFR 872.6475
Regulation Name: Heat Source for Bleaching Teeth
Regulatory Class: I
Product Code: EEG
Dated: February 05, 2007
Received: February 05, 2007

Dear Ms. Creasy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063704

Device Name: BriteWhite Teeth Whitening System

Indications for Use:

BriteWhite Teeth Whitening System is intended to emit light in the 400 nanometer spectrum to provide a light source for the bleaching of teeth.

Prescription Use X
(21 CFR Part 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Infectious Disease New York General Hospital,
Infection Control Unit

510(k) Number: K063704 Page 1 of 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BEKS Incorporated
C/O Ms. Jill Creasy
JC Consulting
694 Bluff Street, #104
Carol Stream, Illinois 60188

FEB 20 2007

Re: K063704

Trade/Device Name: BriteWhite Teeth Whitening System
Regulation Number: 21 CFR 872.6475
Regulation Name: Heat Source for Bleaching Teeth
Regulatory Class: I
Product Code: EEG
Dated: February 05, 2007
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Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

January 30, 2007

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

BEKS INCORPORATED
C/O JC CONSULTING
694 BLUFF STREET # 104
CAROL STREAM, IL 60188
ATTN: JILL CREASY

510(k) Number: K063704
Product: BRITEWHITE TEETH
WHITENING
SYSTEM, MODEL
BW1101

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(1)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 13, 2006

BEKS INCORPORATED
C/O JC CONSULTING
694 BLUFF STREET # 104
CAROL STREAM, IL 60188
ATTN: JILL CREAMY

510(k) Number: K063704
Received: 13-DEC-2006
Product: BRITEWHITE TEETH
WHITENING SYSTEM,
MODEL BW1101

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review:
1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html.
2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).
3) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsb.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K 063704



Cover Letter

December 7, 2006
"510(k) Submission." Traditional,

Submitter/Owner:
BEKS Incorporated
401 14th Avenue NE Unit #2
Jasper, AL 35501
888-582-3650
205-384-3940 Fax

Preparer/Contact Person:
Jill Creasy
JC Consulting
694 Bluff Street #104
Carol Stream, IL 60188
630-480-0476
630-665-3611 Fax
jeconsulting@comcast.net

Common Name: Teeth Whitening System
Proprietary Name: BriteWhite Teeth Whitening System Model #BW1101
Classification Name: Light Source for Bleaching Teeth (21 CFR 872.6475)
Product Code: EEG
Regulatory Class: I
New Device

Predicate Devices: South Beach Smile Light (K042153), QuickSmile (K052040), Omnilux Revive (K030426), Revitalight (K042630)

BriteWhite Teeth Whitening System
BEKS Incorporated
401 14th Avenue NE Unit #2
Jasper, AL 35501
888-582-3650 * 205-384-3940 Fax
www.britewhitesystem.com

RECEIVED
DEC 11 2006
FEDERAL BUREAU OF INVESTIGATION
U.S. DEPARTMENT OF JUSTICE

DE
FI
K18
35

Table of Contents

1. Medical Device User Fee Cover Sheet
2. CDRH Premarket Review Submission Cover Sheet
3. 510K Summary of Safety and Effectiveness
4. Truthful and Accurate Statement
5. Device Manufacture Labeling
6. Device Control Panel
7. Device Operations Manual
8. Device Information / Advertisement
 - a) Counter Top Sign
 - b) Sales Informational Sheet
 - c) Client/Patient Information Brochure

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.htm#3a>. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

BEKS INCORPORATE
694 Bluff Street #104
Carol Stream IL 60188
US

2. CONTACT NAME

Jill Creasy

2.1 E-MAIL ADDRESS

jcconsulting@comcast.net

2.2 TELEPHONE NUMBER (include Area code)

630-4800476

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

630-6653611

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

(b)(4)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/dc/mdufma>)

Select an application type:

- Premarket notification(510(k)); except for third party
- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

3.1 Select one of the types below

- Original Application
- Supplement Types:
- Efficacy (BLA)
- Panel Track (PMA, PMR, PDP)
- Real-Time (PMA, PMR, PDP)
- 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

- YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- The sole purpose of the application is to support conditions of use for a pediatric population
- This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

- YES
- NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

(b)(4)

04-Dec-2006

Form FDA 3601 (08/2003)

"Close Window" Print Cover sheet

37



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 -  [User Fees](#)
 -  [Draft Cover Sheet](#)
 -  [Previous Cover Sheets](#)
 -  [Profile](#)
 -  [Sign Out](#)
- [Medical Device User Fee](#)

 **Confirmation**

YOUR PAYMENT IDENTIFICATION NUMBER IS: MD (b)(4)

Your Cover Sheet has been submitted electronically. You must print and sign the hard copies. Include one in each copy of your application and include a copy with your payment.

[Create Another Cover Sheet](#)

Coversheet

Medical Device User Fee and Modernization Act

[Print/View Final Coversheet](#)

1 Fee: (b)(4)

Total: \$ (b)(4)

Applicant Information

Applicant: BEKS INCORPORATE
 Jill Creasy
 630-4800476
 jcconsulting@comcast.net

Applicant Contact Information

Submitter: Jill Creasy
 BEKS INCORPORATE
 694 Bluff Street #104
 Carol Stream, IL 60188
 UNITED STATES

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38

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 12/07/2006	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input checked="" type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name BEKS Incorporated		Establishment Registration Number (if known)	
Division Name (if applicable)		Phone Number (including area code) (888) 582-3650	
Street Address 401 14th Avenue Unit #2		FAX Number (including area code) (205) 384-3940	
City Jasper	State / Province AL	ZIP/Postal Code 35501	Country USA
Contact Name Jill Creasy			
Contact Title PPOC		Contact E-mail Address jcconsulting@comcast.net	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name JC Consulting			
Division Name (if applicable)		Phone Number (including area code) (630) 480-0476	
Street Address 694 Bluff Street #104		FAX Number (including area code) (630) 665-3611	
City Carol Stream	State / Province IL	ZIP/Postal Code 60188	Country USA
Contact Name Jill Creasy			
Contact Title PPOC		Contact E-mail Address jcconsulting@comcast.net	

39

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (specify):

SECTION D2

REASON FOR APPLICATION - IDE

<input checked="" type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (specify):

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	EEG	2	GEX	3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K042153	South Beach Smile Light Whitening System	Dentovations Inc
2	K052040	QuickSmile	Cosmetic Dental Materials Inc.
3	K0030426	Omniflux Revive and Blue	Photo Therapeutics Limited
4	K042630	Revitalight Skin Care System	Skincare Technology
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
Whitening Light System

	Trade or Proprietary or Model Name for This Device	Model Number
1	BriteWhite Teeth Whitening System	BW1101
2		
3		
4		
5		

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section (if applicable)	Device Class
EEG	21 CFR 872.6475	<input checked="" type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel		

Indications (from labeling)

Light source for whitening teeth, temporary relief of minor muscle pain and promoting relaxation of muscle tissue

41

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name BEKS Incorporated			Establishment Registration Number		
Division Name <i>(if applicable)</i>			Phone Number <i>(including area code)</i> (888) 582-3650		
Street Address 401 14th Avenue Unit #2			FAX Number <i>(including area code)</i> (205) 384-3940		
City Jasper		State / Province AL	ZIP/Postal Code 35501	Country USA	
Contact Name Jill Creasy		Contact Title PPOC		Contact E-mail Address jcconsulting@comcast.net	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name <i>(if applicable)</i>			Phone Number <i>(including area code)</i> ()		
Street Address			FAX Number <i>(including area code)</i> ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name <i>(if applicable)</i>			Phone Number <i>(including area code)</i> ()		
Street Address			FAX Number <i>(including area code)</i> ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

42

SECTION I

UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

1063704

**FDA 510K Summary of Safety and Effectiveness for
BriteWhite Teeth Whitening System Professional**

1. General Information

Submitter: BEKS Incorporate
401 14th Avenue NE Unit #2
Jasper, AL 35501
888-582-3650
205-384-3940 Fax

Contact Person: Jill Creasy
JC Consulting
694 Bluff St. #104
Carol Stream, IL 60188
630-480-0476
jcconsulting@comcast.net

Summary Preparation Date: December 3, 2006

2. Device Name

Proprietary Name: BriteWhite Teeth Whitening System (Professional)

Classification Name: Light source for bleaching teeth (21 CFR 872.6475).

3. Predicate Device

The BriteWhite Teeth Whitening System Professional is substantially equivalent in respect to the intended use, design and method of operation to numerous cleared devices, including; the South Beach Smile Light Whitening System (K042153), QuickSmile (K052040), Omnilux Revive (K030426) and RevLight (K042630)

4. Device Description

The BriteWhite Teeth Whitening System device that utilizes Light Emitting Diodes to provide a tooth whitening system, the whitening light source is a mouth piece which is placed inside the mouth, using barrier sleeves, which emits a biologically safe and effective level of blue visible light. The general wavelength for the mouth piece is 400 nanometer spectrums to provide a selected wavelength which activates the whitening gel to bleach the teeth without the aide of heat. The second detachable mouth piece provides LED light to the body in the 600 nanometers. To ensure user safety when operating the light, the system has a built in feature to eliminate any risk for the end user and professional. The light automatically shuts off after a specified period of time. Secondly, the light source in placed inside the mouth, so there is no need for safety glasses for the patient and professional. No contact with the eyes is in this area of treatment and prevents penetrations of blue/red wavelength and protects the vision of the patient and professional.

5. Indications for Use:

1. The BriteWhite Teeth Whitening System is intended to emit light in the 400 nanometer spectrums to provide a light source for bleaching of teeth.
2. The BriteWhite detachable mouth piece (Red) is intended to emit light in the 600 nanometer spectrum is generally indicated, to provide topical heating to promote increased blood flow, the temporary relief of minor muscle and joint pain, relieving stiffness and promoting relaxation of muscle tissue.

6. Technical Characteristics

The BriteWhite Teeth Whitening System and the aforementioned predicate devices are the light source for bleaching teeth as defined in 21 CFR 898.6475 and 21 CFR 878.4810

The BriteWhite Teeth Whitening System is an economical tooth whitening light which in conjunction with the whitening gel and tooth whitening preconditioning mouth wash provides a light source for bleaching the teeth. The BriteWhite Teeth Whitening System has similar intended use and technological characteristics to the predicate devices. The primary difference is the BriteWhite Teeth Whitening System uses an inside the mouth, hand piece and provides a second detachable mouth piece for the use of topical heating to promote increased blood flow, the temporary relief of minor muscle and joint pain, relieving stiffness and promoting relaxation of muscle tissue.

7. Conclusions

The BEKS Inc. BriteWhite Teeth Whitening System has the same intended use, with similar functional and performance characteristics. The BEKS Inc. BriteWhite Teeth Whitening System performs as intended and does not raise any new safety or efficacy issues.

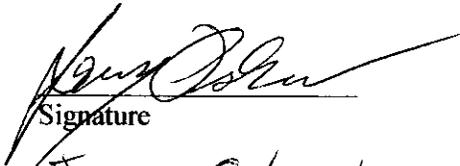
1K063704



Premarket Notification Truthful and Accurate Statement

(As Required by 21 CFR 807.87(k))

I certify that, in my capacity as President/Developer of BEKS Incorporated, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.


Signature

Joyce Osborn
Printed Name

12/7/06
Date

BriteWhite Teeth Whitening System
BEKS Incorporated
401 14th Avenue NE Unit #2
Jasper, AL 35501
888-582-3650 * 205-384-3940 Fax
www.britewhitesystem.com

46

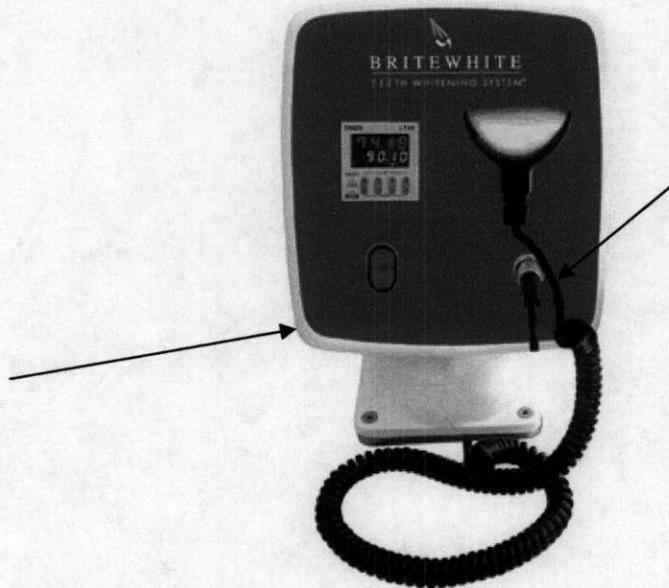
Manufacturers Details

Location of Manufacturer labels

Label #1 – Identification and Certification - Base Unit

- Model Number
- Serial Number
- Date of Manufacture

This label is located on the back of the base



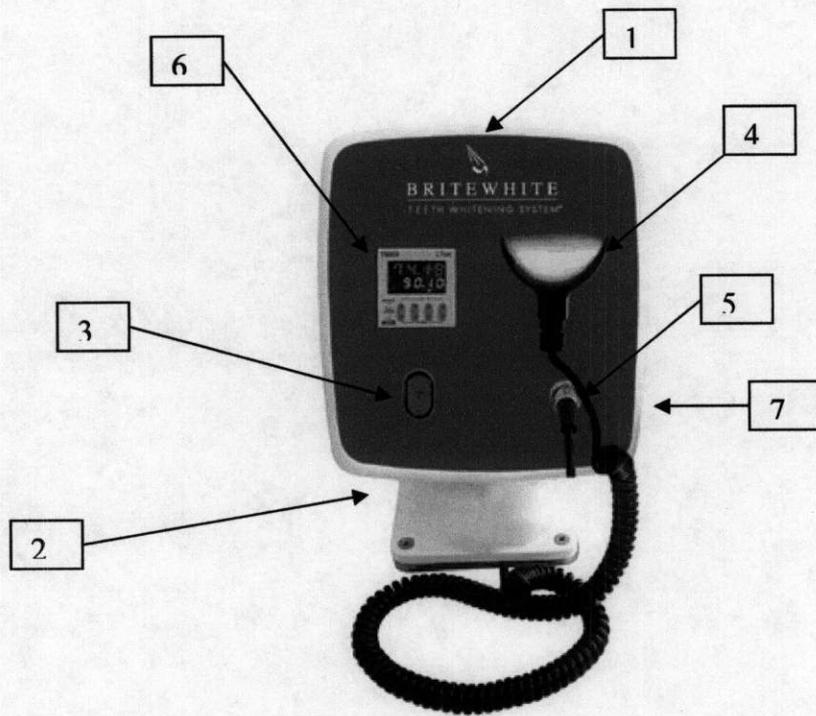
Labels #2 – Identification and Certification – Mouth Piece

- Model Number
- Serial Number
- Date of Manufacture

These labels are located on the cord of each Mouth Piece

BEKS Incorporate
Toll Free 888-582-3650
www.britewhitesystem.com

BriteWhite Teeth Whitening System Control Panel



1. System Base
3. Power Switch
5. Mouth Piece Connector
7. Power supply reset button

2. Power Supply Cord
4. Mouth Piece
6. Treatment Timer

BEKS Incorporate
Toll Free 888-582-3650
www.britewhitesystem.com



B R I T E W H I T E

T E E T H W H I T E N I N G S Y S T E M tm

A cool new way to whiten teeth...

LED Light Emitting Diode's
Blue LED Light For Whitening Teeth
Red LED Light for relaxation of Muscle Tissue

**TEETH WHITENING
TREATMENT MANUAL**

BEKS Incorporated — 401 14th Avenue N.E., Unit #2, Jasper, AL 35504
Toll free 88/582-3650 — Direct 205/384-3640 — Fax 205/384-3910 —
Email — josborn@britewhitesystem.com
Global Patent Pending
www.britewhitesystem.com

INDEX

SUBJECT	PAGE
Introduction	3
How BriteWhite Teeth Whitening Works	4
Control Panel	5
Manufacture Details	6
Machine and Maintenance	7
Warranty	9
Insurance and Liability	10
Causes for unsightly teeth	11
Indications for use	17
Contraindications	18
Start-Up Kit (Optional Products/Attachments)	19
Consultation	21
Pre Treatment	22
Consent Form	23
Post Treatment	24
Treatment Protocol/Polish and Plaque Removal	25
Treatment Protocol/Teeth Whitening	26
Treatment Protocol/Red LED Mouthpiece	35
Summary	37
Activating Gel	38
Glossary	39

INTRODUCING BriteWhite FOR YOU

BriteWhite Teeth Whitening System™ offers the first LED light emitting diode system that is inserted “in-the-mouth” for the ultimate in Professional teeth whitening.

BriteWhite offers advance whitening agents for quicker and safer results without the aid of heat. You can now offer your patients the revolutionary quickest, safest, and user friendly, whitening system for the most effective white teeth on the market. Our Products do not have Hydrogen Peroxide, Fluoride or Alcohol ingredients maintaining the safest products to offer our clients/patients.

BriteWhite Teeth Whitening System™ takes less time to get snow-white teeth using a cool array of LED Light Emitting Diodes.

- No Heat
- No Saliva Drips
- No Cheek Retractors or Rubber Dams
- No Pain
- No Trays
- No Gagging
- No Safety Eyewear
- Non-invasive

Less time promotes whitening without softening enamel, causing corrosive problems, or the disruption of soft and hard tissues and preventing damage to the pulp. These gentle blue cool LED Lights activates the whitening gel to remove years of discolorations from the teeth, including improving those teeth discolored by tetracycline and Minocycline..

BriteWhite Teeth Whitening System™ offers a special custom blend of gel for bleaching. This combination of whitening gel gives your Patients a product for teeth whitening, unlike other products, eliminating discomfort for most. We are excited to give you a system that will bring you higher revenue returns and cutting down overhead. You have the exciting opportunity to offer for the first time the cutting edge for whiter teeth the cool way without touching the teeth.

We, at **BriteWhite Teeth Whitening**, thank you for giving us the opportunity to work as a team for healthier and whiter teeth at the most affordable prices. We expect the rewards for offering our system to be profitable. You receive a Start-Up Kit, including the Instructional Manual, and enough products for three clients/patients. Our system offers a complete line of products for maintenance.

Our manual is simple and easy to understand and designed for your convenience. Our product is user friendly. Our goal is a long-term relationship. We welcome you the opportunity to offer for the first time our “**BriteWhite**” Teeth Whitening System™ to add to your repertoire of services. Our commitment to the industry’s satisfaction for teeth whitening sets us apart from the competition.

Joyce Osborn/President/Developer

Contact your local Distributor today for more details

Global Patent Pending/US Made
A Cool Way to Whiten Teeth Safely.....

How BriteWhite Teeth Whitening Works

Results for whitening teeth are obtained by attacking the discolorations of the teeth. A specifically tailored gel and a specific wavelength (nanometer) and power (mw) mill watt are combined to boost the delivery of the light and gel to all teeth. The upper and lower, inside and outside, cover all areas of the reach to whiten teeth simultaneously.

BriteWhite Teeth Whitening, sold **only** to Professionals, is the first Blue LED Light System globally to have a new advanced system for whitening teeth quickly and safely. The approach to this new method is achieved by using a custom blend gel to the teeth and placing the Blue LED probe **inside** the mouth. LED Light activates the gel by coming in direct contact with the teeth attacking the "discolorations" only without affecting the enamel or pulp. This direct approach has also proven to be quicker, safer and causes less sensitivity than other light systems for whitening teeth. Unlike over-the-counter (OTC) Products, **BriteWhite** is only used and sold by Professionals to prevent harmful side effects.

A Shade Guide is recommended to be used for determining the shade prior to beginning each treatment. Up to 11 shades whiter in less than 15 minutes on aged teeth has been achieved through this exciting new whitening system and without sensitivity.

Patients having a problem with gag reflex or anxiety do not experience problems with this exciting technology. Various colors of teeth take on different shades of lightening. Yellow and brown respond better than tetracycline. Grey shades may take longer. A follow-up treatment may be suggested for hard to whiten teeth.

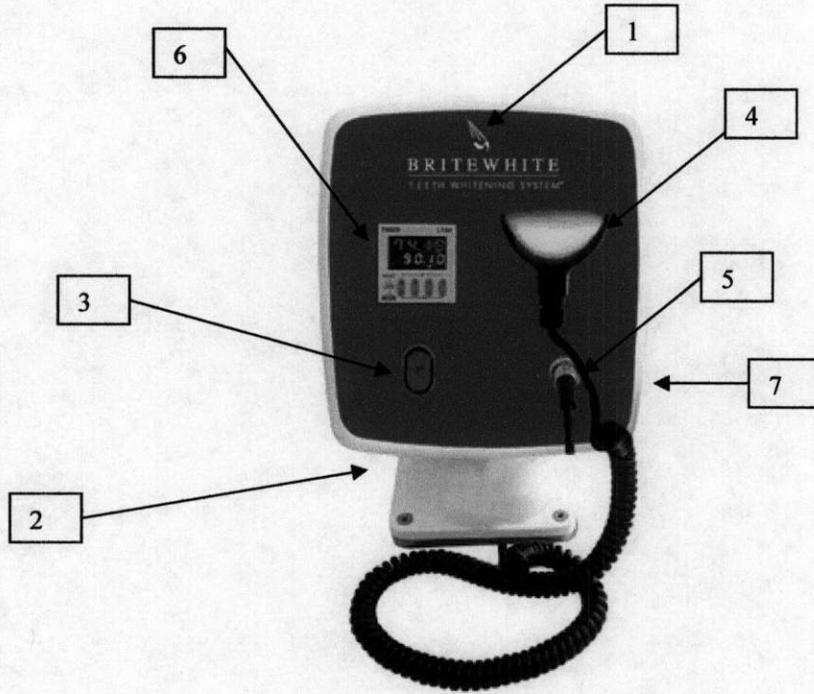


Photo by JoyceOsborn

BriteWhite Teeth Whitening System™ is designed for no maintenance, user friendly and comfort for the patient. The timer is pre-set at 90 second intervals using the ON/OFF with an easy RED reset button after each 60 second off cycle. 90 on/60 off in between each 90 seconds to prevent overheating and promoting the lifetime of the LED's – 4 cycles to complete one treatment cycle, **average treatment time 4 – 90 second cycles.**

BriteWhite Teeth Whitening System

Control Panel



- 1. System Base
- 3. Power Switch
- 5. Mouth Piece Connector
- 7. Power supply reset button

- 2. Power Supply Cord
- 4. Mouth Piece
- 6. Treatment Timer

BEKS Incorporate
Toll Free 888-582-3650
www.britewhitesystem.com

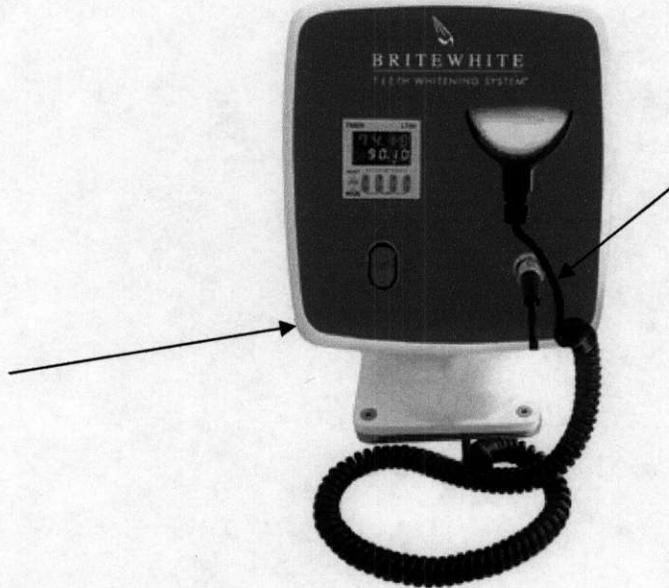
Manufacturers Details

Location of Manufacturer labels

Label #1 – Identification and Certification - Base Unit

- Model Number
- Serial Number
- Date of Manufacture

This label is located on the back of the base



Labels #2 – Identification and Certification – Mouth Piece

- Model Number
- Serial Number
- Date of Manufacture

These labels are located on the cord of each Mouth Piece

BEKS Incorporate
Toll Free 888-582-3650
www.britewhitesystem.com

Machine and Maintenance

Parts Replacements:

Parts replacement or additional probes can be purchased by credit card.

Return Authorization:

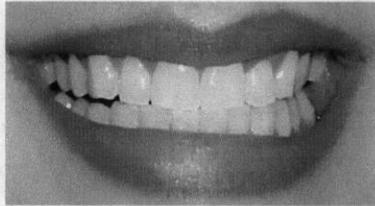
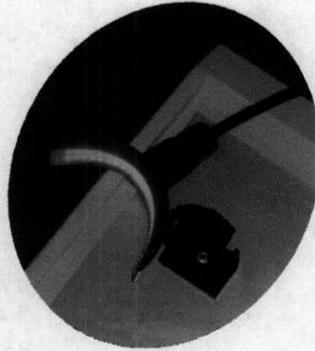
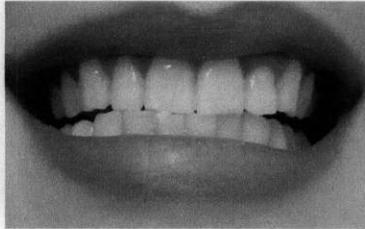
For return authorization, please contact the company for return policy. If device needs to be replaced or returned for repair while under warranty, the company will provide a loaner. Customer pays shipping only.

BENEFITS OF LED – LIGHT EMITTING DIODE

**Light Emitting Diodes have a long life span and 2 – 3 times more powerful than the halogen. The Blue LED took twenty (20) years to develop. The BriteWhite timer is preset for 90 seconds on, automatically shutting the blue LED mouthpiece lights off. The lights should remain off for a full 60 seconds in between treatment time. The 60 seconds off allows the LED's to cool down and eliminate heat build up, maintaining the lifetime of the LED's. We do not offer refunds; however, we do offer replacement under our Warranty Program.*

**401 14th Avenue NE, Unit #2
Jasper, AL 35501
FAX 205/384-3910**

BEKS Incorporated - Toll Free 888/582-3650



A revolutionary new teeth whitening system from **BEKS Incorporated**.
BriteWhite Teeth Whitening System™ is the first Blue LED Light to be used inside
the mouth for Professional teeth whitening.

Simple – Safe – Easy – Quick - User Friendly – No Brainer

Enjoy the luxury of this quick, new, exciting system to make your teeth appear to
glow in the dark. **A cool way to whiten teeth safely.**
BriteWhite offers a complete After Care Kit for maintaining your new “cool” white teeth.

Warranty

Warranty covers parts and labor "only" on defects in material or workmanship for a period of one (1) year from the date of purchase. Loaner will be provided by the Company.

Under no circumstances will we, BEKS, Incorporated, be responsible for implied warranties, guarantees, refunds or promises made by our suppliers, assume the entire cost of all necessary servicing, repair or corrections to the BriteWhite System other than those directly made by BEKS Incorporated. We, BEKS Incorporated, disclaim all warranties, express or implied, will not be responsible for refund offers and lifetime warranties, do not endorse other products to be used with the BriteWhite System, other than those endorsed by BEKS Incorporated. Under no circumstances will we be liable for negligence from the use of, or the misuse of our product.

Made in USA/Global Patent Pending

IMPORTANT: The warranty does not cover damages caused by improper use of the equipment, or any attempt to be repaired other than that of **BEKS**, Inc. or any damages caused by accidents.

(Accessories are not covered by this warranty).

Proof of purchase, with Serial Number, is needed to provide warranty service on your **BriteWhite** Teeth Whitening System to:

Warranties offered for more than One Year will be null and void by BEKS Incorporated. BEKS Incorporated will not be responsible for any liabilities or claims through any sources not authorized by the Company (BEKS Incorporated). All inquiries should be directed to:

BEKS Incorporated

401 14th Avenue N. E., Unit #2, Jasper, AL 35504

Toll Free 888/582-3650 – Direct 205/384-3640 - Fax 205/384-3910

NOTE: *Warranty is null and void if other products are attempted to be used with BriteWhite Teeth Whitening System[™]. Products not designed for the high quality mouthpiece can cause damage to the surface and affect the quality of the results.*

INSURANCE AND LIABILITY

Check with each State regulations and requirements for teeth whitening in salon/spa.

LIABILITY

Proof of liability insurance must be provided by the client to the company prior to the shipment of BriteWhite Teeth Whitening System.

Insurance is available through "Insurtec Insurance Company." This company is rated A+ by America's Best. Toll Free 800/606-0621 – Fax 417/395-2713. Coverage is offered for BriteWhite, a complete package for the spa/salons or to Medical Spas. For more information call your distributor.

BEKS Incorporated, *under no circumstances, will be responsible for any claims, liabilities, or negligence in the use of BriteWhite Teeth Whitening. Follow manufacturing directions for the use of the BriteWhite Teeth Whitening System[™].*

CAUSES FOR UNSIGHTLY TEETH

Unsightly teeth are caused by a variation of problems:

- ◆ Illness (High Fever causes yellow teeth)
- ◆ Aging
- ◆ Tetracycline and Minocycline
- ◆ Red Wine
- ◆ Blueberries
- ◆ Tea
- ◆ Coffee
- ◆ Soy Sauce
- ◆ Cigarettes
- ◆ Antibiotics

The first step for successful teeth whitening is to remove surface discolorations.

This reveals discolored fillings, the more resistant, deeply imbedded enamel and dentin discolorations. Your teeth are made up of an inner dentin layer and a hard outer enamel layer which protects the teeth. Discolorations from food, cigarette smoke, etc., form a top layer on top of the enamel layer, accumulating a pellicle film over the enamel layer. As this pellicle layer sits on your teeth for years, the foreign material gets into the enamel. The enamel, "simply put," is porous, which

means staining agents can work their way down into the tooth. These deep discolorations are harmless, but unattractive. Teeth Whitening gels go beneath the surface attacking the discolorations beyond the toothbrush or where whitening strips do not reach. Whitening Strips lay flat to the teeth without penetrating cracks and crevices. The **BriteWhite** Activator is a special custom blend gel that penetrates and attacks these unsightly discolorations without sensitivity for most.

Across the counter products (OTC) can be helpful, but can also be ineffective or harmful. Some OTC products have been found to contain "meat tenderizers." Whitening teeth properly should be under professional care with follow-up for maintenance. **Phasing whitening treatments is first to professionally whiten the teeth and second maintaining the brightest shade by following manufacturers directions for home maintenance.** Sensitive teeth may be slightly dehydrated and easily discolored from foods or drinks. (Use straws for drinking, etc.) Proper after care, using the instructions for keeping teeth white will prevent resurface discoloring and prevent irritation or problems that are caused by the untrained public. Proper teeth whitening is the obligation of oral health care technicians.

Over bleaching, done by untrained technicians from home kits, often cause the appearance of chalky and translucent teeth. Tetracycline-discolored teeth respond after giving persistent treatments, which include an increased number of treatments. Tetracycline discolorations go beyond the enamel and deep into the

dentin of the tooth. They will respond to bleaching depending on the color and intensity of the color. Banded color, from braces, is more resistant to bleaching agents.

Age-related color responds well to bleaching.

Discolorations include colors that range from yellow-brown, shades of grey and/or a combination of yellow and grey. **Yellow, caused from food, etc., is removed more easily than brown, grey or grey-brown (such as Tetracycline).**

Other discolorations, the most common and easy to remove, are those caused by coffee, tea, wine, tobacco, or one's own metabolic processes.

BriteWhite's State of the Art LED technology is unlike other teeth whitening devices currently on the market and utilizes the Blue LED inside-the-mouth for the ultimate in teeth whitening. Blue LED has provided the source to kill bacteria that cause periodontal disease. **BriteWhite** is the first inside-the-mouth professional teeth whitening system globally to provide the pathway to healthier gums and teeth. The Blue LED has proven to be safe without side effects utilizing the Blue LED wavelength to activate the special blend of ingredients in their dual activator to attack the discolorations without softening the enamel or damaging the pulp. **There has been no documentation of side effects with the use of LED light therapy.** Blue LED has already received FDA approval for killing the "P" bacteria that causes acne. Unlike the Zoom and BriteSmile, that

treat the front teeth, and use hydrogen peroxide with heat, **BriteWhite** treats “all” teeth, front and back and gums that benefit from the Blue LED without heat.

BriteWhite is alcohol free (causes the teeth to become dehydrated), and fluoride free (researchers suspect overuse of fluoride can cause tooth decay).

BriteWhite does not recommend any over-the-counter products or whitening without professional supervision.

Sometimes, cracks can cause sensitivity during bleaching (recommend a dentist). These should be noted on the history of the patient. Bands from braces and trauma areas will most likely not be removed. ***Lighter decalcified areas should be noted because these areas may be intensified, making them lighter at the beginning. After continued treatments for bleaching, these areas will often blend.*** Proper rinsing after your treatment with **BriteWhite’s After Rinse** will neutralize the teeth. For home maintenance, the **BriteWhite Mouthwash**, which kills bacteria, prevents bad breath, helps relieve irritations and helps reduce sensitivity. (All products manufactured for **BriteWhite** are FDA approved manufacturing companies.) It is also recommended for those using braces. **BriteWhite Mouthwash** is safe for all ages, alcohol free and does not dry soft tissues.

BriteWhite Cleansing Gel (toothpaste) is a special blend that alters dental problems, improves everyday oral hygiene and boosts whitening. If bleaching a single tooth, the tooth will need special attention before it blends with the other teeth.

****Sometimes it is best to suggest restorative means.***

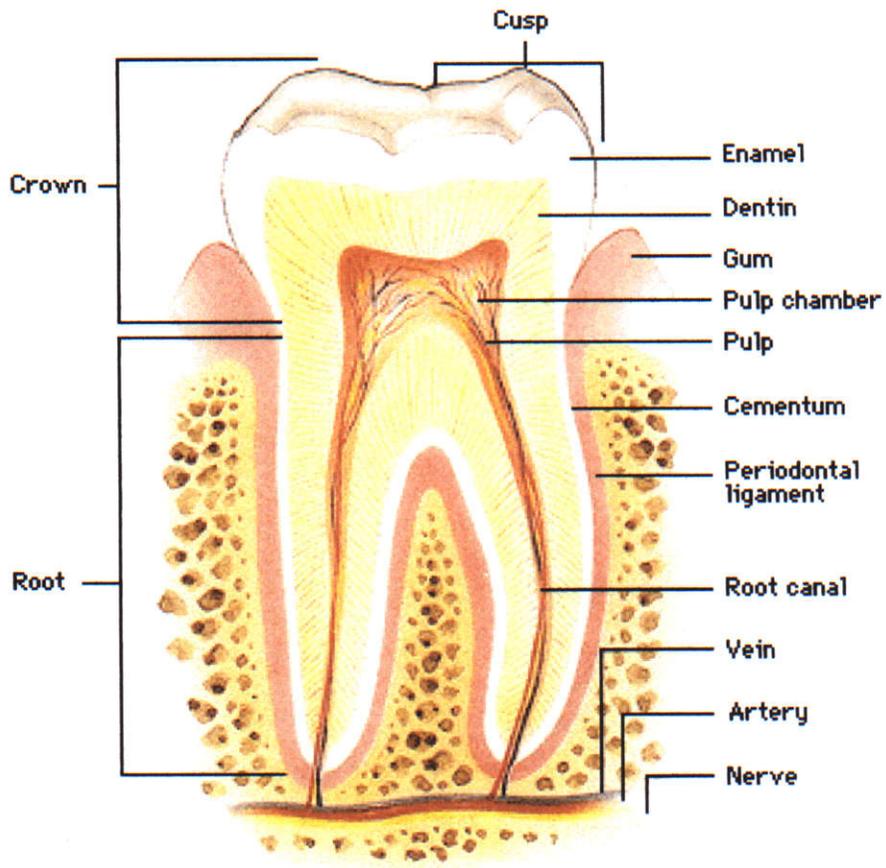
Expect some fading without using the Home Maintenance **BriteWhite** Kit to maintain the original color. Proper after care is vital as the saliva re-mineralizes the enamel. Daily use of the **BriteWhite** After Care should be advised to prevent the teeth from becoming discolored. Some drugs can cause teeth discoloration, other than those known by the Tetracycline, such as Minocycline, used to control acne and other skin problems.

With **BriteWhite** home care, it is **not necessary** to wear the trays overnight.

This can cause over bleaching. For maintenance, use trays after wine, or any color related drinks and foods for 15 - 30 minutes. All bleaching products gradually lose strength and are diluted by the saliva causing the product to stop its active action.

Whitening gels will not whiten old restorations, fillings or crowns.

Structure of the tooth



INDICATIONS FOR USE

Benefits of LED (Light Emitting Diode):

Longer life span

No need for filters

No need for cooling fan

No decrease of light output over the life time of the light device

No disruptive of soft and hard tissues

Takes less time for whitening without softening enamel or causing corrosive problems.

BriteWhite Teeth Whitening System will bring higher revenue returns.

Comfort for client/patient:

- Gingival Protection is Optional
- No Patient Sensitivity (most) New improved LED light is used for fast and effective whitening
- Non-Laser whitening procedure
- No long waiting
- No gagging
- No saliva drips
- No softening of enamel
- No Protective Eyewear needed.

CONTRAINDICATIONS FOR USE

Contraindications, risk and what to expect during your whitening procedure:

Liability:

ADA approved the use of 10% Carbamide Peroxide
Dental office use both Carbamide Peroxide and Hydrogen Peroxide in higher concentrations.

Esthetic Industry are allowed in most states to use up to 22% Carbamide Peroxide

Each State varies - check restrictions for use under esthetic care

BriteWhite has a special dual activator for removing stains safely

Patients with decayed teeth, infected gums, white spots on their teeth, and multiple tooth colored fillings or crowns (caps) on the front teeth may not be a good candidate for tooth whitening.

***Contraindications: Evaluation before whitening for no cavities, and all fillings, crowns, root canal, etc., should be completely coated with BriteWhite Protective. Note the following:**

Any Loss of Enamel
Allergies

16 Years or older (**under 16 parental consent required**)

NO Pregnancy and nursing

Large Pulp (*adolescence pulps have not matured – pulps shrink with age*)

Carious Lesions

Any Suspicious Areas

Periodontal Disease

Start-Up Kit/Optional Products/Attachments

Start-Up Professional Kit Includes:

- Three (3) BriteWhite Single Whitening Activators *(dual activator is also offered)*
- Three (3) BriteWhite After Rinse *(neutralizing rinse)*
- Three (3) BriteWhite Trays and Case *(post treatment)*
- One (1) BriteWhite Protective *(used for blanching or sensitivity)*
- One (1) BriteWhite Polishing Tool *(complimentary one time only)*
- One (1) BriteWhite Polishing Paste
- One (1) Disposable Mouth Covers (100 pak)
- Two (2) Shade Guides

Instruction Manual
Marketing Material

Disposables Include:

- BriteWhite Tray and Custom Case *(post treatment)*
- BriteWhite Activator *(whitening aftercare activator for home)*
- BriteWhite Cleansing Gel *(toothpaste)*
- BriteWhite Mouthwash *(kills bacteria)*
- BriteWhite Protective *(protective coating must be used for gingival for blanching, chipped teeth, problem areas for protection against sensitivity, crowns, etc.)*
- BriteWhite Polishing Paste *(Removing Plaque, Tartar and after Polishing))*
- BriteWhite Sponge Applicator *(Apply Protective to gingival/lips is needed for blanching)*
- BriteWhite Brush Applicator *(to help fill activator between teeth if needed)*
- BriteWhite Marketing *(See Order Form)*

(Now available the optional Red LED Mouthpiece)

BriteWhite Teeth Whitening System will bring you high revenue returns:

Fast

Upper and lower arches at the same time

Cleanse Teeth or have professionally cleaned prior to whitening treatment

No paint on dam or rubber dams

No cheek retractors

No dehydration

No heat

No trays

No need for safety glasses

Non-invasive

Non-Laser Whitening Treatment

No need for "hot" peroxides

Less Sensitivity (Most experience no sensitivity)

Portable Table Top

Lightweight

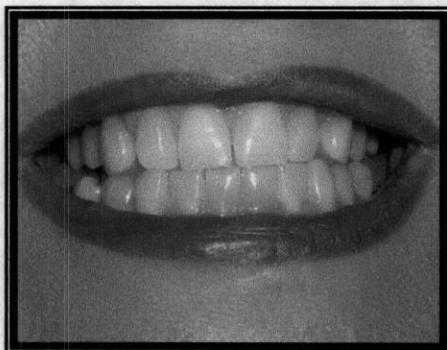
Used by dentist/hygienist/esthetic industry

Simple to use

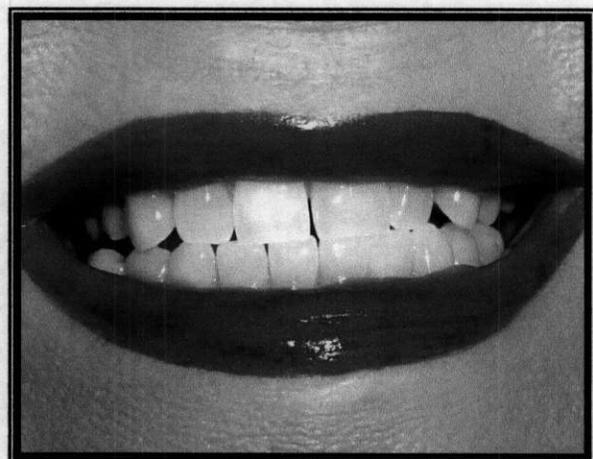
Blue LED used for teeth whitening and Red LED to promote increased blood flow, relaxation of muscle and relief of joint pain. (Red LED is an optional detachable mouth piece)

Amazing Results!

Marketing Material Included in Introductory Offer.....



Before



After

CONSULTATION

BriteWhite is a cool way to whiten teeth

DO NOT promise or indicate guaranteed results

NOTE: (A professional cleaning is recommended prior to any teeth whitening treatments)

***Whitening varies from patient to patient depending on age, life style (smoking, etc.) and medicinal history, antibiotics, etc..**

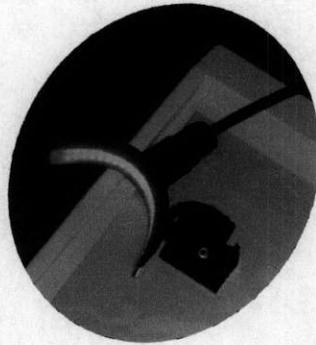
Determine Tooth Shade

Take Pictures before and after

Explain the procedure

Go over Consent Form and answer any questions

Explain possible sensitivity



Go over Post Treatment instructions for maintaining white teeth



Pre Treatment

BriteWhite whitens all teeth in one sitting

For best results for professional teeth whitening:

- 1) Have your teeth professionally cleaned if needed prior to your whitening treatment or use Polishing Tool Attachment with Polishing Paste for pretreatment to boost the results.
- 2) No heavy brushing and no flossing prior to treatment.



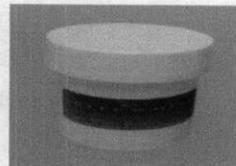
Cleansing Gel



Mouthwash



After Rinse



Polishing Paste



Protective



Consent Form BriteWhite Teeth Whitening

I fully understand that the effect for whitening may vary and agree that the total liability is limited to the amount of the cost for whitening my teeth.

There is no guarantee to the final result.

- I do not have any decayed or loose teeth.
- My teeth may not result in noticeable lightening because of the color of my teeth and some forms of stains, which include yellowing from high fever or medication.
- Trauma within the past 12 months may turn dark and may need a root canal.
- I will consult a physician if I experience any problems from the treatment of this product.
- Teeth showing shades of grayish or dark-brown may be the result of nerve death and/or root canal and will not respond to whitening. The teeth may require a root canal.
- Hard to whiten teeth may require more than one treatment.
- Discolorations from products include; coffee, wine, tea, curry, saffron, paprika, cigarette smoking, tobacco, turmeric, beverages, colas, ice tea, mustard ketchup and others. I must avoid these products for three (3) days after whitening.
- I understand that the procedure is not for crowns, veneers, fillings, bridges, and bonds have no guarantee as to the results, sensitivity or duration of the shades lightened.
- I understand a BriteWhite After Care Kit is suggested for maintaining my white teeth at an additional cost.
- I understand the terms/ conditions giving my consent for the BriteWhite teeth whitening treatment.

DATE: _____

Patient/Parent Consent (If under 16 years of age):

Signature _____ **Address** _____

City _____ **State** _____ **ZipCode** _____

Print Name _____ **Phone** _____

Professional Technician _____

Approximate Start Teeth Shade _____ Ending Teeth Shade _____

COMMENTS: _____

POST TREATMENT For Maintaining White Teeth

Maintenance Kit for Home includes:

Boil N' Bite Tray with Case
Activating Gel
Cleansing Gel (Toothpaste)
Mouthwash

After you have received your Professional BriteWhite treatment, follow the post treatment directions. A cool way to keep your teeth white:

- 1) **To mold Boil N' Bite Trays** to the mouth, hold the tray by the "holding lip," dip in very hot water – near boiling, until the tray begins to "wilt." Take out immediately and mold to the teeth. If the tray does not mold on your first attempt, dip the tray again, but DO NOT allow the plastic to mold together. When the tray fits properly, cut off the "holding lip," and trim any access plastic that does not feel comfortable and store in the tray case. See below.
- 2) **Avoid staining foods** for the first day and **extreme temperatures** for two (2) days. The treatment removes your protective outer layer, which can cause color change if ingesting anything colorful during this time period. You may expect a shade to recede very slightly after the first couple of days. Brush only with **BriteWhite Cleansing Gel (toothpaste)** preventing discolorations from reattaching to the tooth's surface.
- 3) After brushing, rinse with **BriteWhite Mouthwash** Swoosh in mouth 30 seconds on a daily basis. BriteWhite Mouthwash kills bacteria.
- 4) Do not use anything with an alcohol base. The chemicals can drastically affect the results of your whitening treatment.
- 5) Use your **BriteWhite Trays with BriteWhite Dual Activator** once daily for 30 – 40 minutes the first 7 days after your professional treatment and when boosting treatments are needed.
- 6) If sensitive, use **BriteWhite Cleansing Gel in your tray, wearing 15 minutes prior to your boosting treatment,** to ensure no sensitivity.

Example below of before and after molding your tray and can be remolded.



Before Molding



After Molding and trimmed

TREATMENT PROTOCOL FOR POLISHING AND PLAQUE REMOVER

Before using the Polish, tartar and plaque removal tool, brush teeth to remove unwanted residue:

1. Direct the client/patient to place one small amount of teeth polishing paste to the back of the gloved hand. Snap on the Disposable Prophy Cup and dip the Polishing disk into the paste filling the cup.
2. Without using pressure, begin by using a light touch. **DO NOT** spend more than a few seconds on each tooth. If the tooth becomes warm, too much pressure is being applied. Rinse, dry teeth and begin teeth whitening treatment.
3. After whitening treatment, polishing can resume repeating Steps 1 and 2. Rinse, gently brush the paste from the teeth, and rinse with after rinse for 30 seconds. Go over Post Treatment Instructions for home.

. Use 2 “AA” batteries.

DO NOT use on children under 13 years of age.

TREATMENT PROTOCOL/Teeth Whitening

BriteWhite's Dual Activating Gel is a patented product. The bleaching agent, (breaks down to 15/16% Carbamide Peroxide) and catalyst are equally mixed with the "turbo" tip to alleviate discomfort to the gingiva and teeth. Carbamide Peroxide has a long shelf life, 18 months (under refrigeration up to 2-3 years), Hydrogen Peroxide has a very short shelf life.

Instruct patient/client to gently brush and floss the teeth prior to treatment.

- 1) Determine the existing shade by using a Shade Guide, write down the beginning shade for each patient.
- 2) Determine existing shade (with teeth moist and without overhead light).
- 3) Take pre-op photos, apply gloves and magnifying glasses.
- 4) **For best results – pre prep:** (extra charge to be added to the whitening treatment) using the **BriteWhite Polishing Tool** and the **BriteWhite Tartar and Polishing Paste**. Removes stubborn discolorations and built up tartar and plaque. It will also help remove plaque that ordinary brushing cannot do. Pre cleaning the teeth surfaces, removing discolorations before teeth whitening will increase the effectiveness of the whitening treatment. **Do not use any substances that could interfere with the whitening process. Use only BriteWhite whitening products to insure warranty.** Chemicals in some products can discolor the teeth. Concentrate on yellow cervical areas of upper and lower teeth. If desired, the lingual areas can also be pumiced to remove discolorations and provide a better overall result. ***Good preparation is the key to successful results.***

5) For tetracycline or A3.5 or darker shades, apply a 5-second acid etch
(dentist only) to the teeth (optional).

Instruct the client/patient to gently dry teeth and gingival. Conventional rubber dams are not recommended for the **BriteWhite** Teeth Whitening System. If the patient has an overlapping bite, placing a half cotton roll in between the first and second molars will increase client/patient comfort.

Apply BriteWhite Protective to gold teeth and sensitive areas if needed.

Remove the tip from **BriteWhite Dual Whitening Activator** syringe. Instruct the client/patient to apply a Disposable Cover (**Barrier Sleeve**) to the Mouthpiece, molding it to the Mouthpiece and twisting it to keep in place.

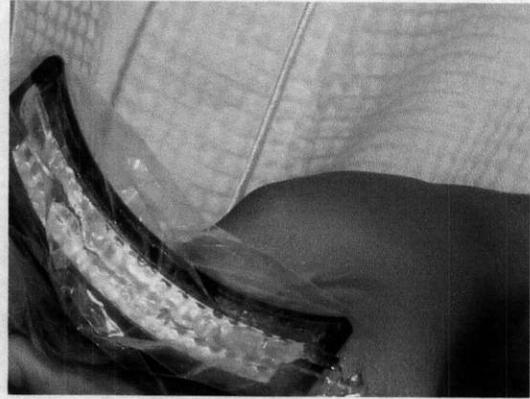
Shading the teeth



Instructing the application of Activating Gel



Applying Gel directly to the Mouthpiece



Correctly inserting the mouthpiece directly to the teeth keeping bite plate together



Technician instructing client

Resetting the "RED" reset button beginning 90 second cycle



Removing Saliva, gel and Disposable Sanitary Mouth Cover



- 1 – Fill out the Consent Form
- 2 - Shade the Teeth charting the shade
Instruct client/patient to remove discolorations if necessary with tartar tool (add on service)
- 3 – Ask patient/client to gently blot the teeth and gingiva
- 4 - Put a Disposable Cover (Barrier Sleeve) on the mouthpiece, molding it to the concave of the mouthpiece and twisting to hold in place. Direct the patient/client how to apply gel and insert the mouthpiece into the mouth.
- 5 – **DO NOT APPLY THE ACTIVATING GEL DIRECTLY TO THE TEETH.** Apply the Activating Gel directly to the center of the LED tip to tip lights (the concave part of the Mouthpiece). Instruct the patient/client to insert the mouthpiece in the mouth - starting at the

corner at an angle and placing it directly against the teeth. Holding the other side of the mouth open helps place the mouthpiece correctly and directly against the teeth.

7 - Turn on machine. It auto counts 90 seconds at which time it shuts off the "Blue" LED light.

It does not shut off the machine.

The first cycle would be:

- 1 - 90 seconds on/60 seconds off DO NOT REMOVE MOUTHPIECE
- 2 - 90 seconds on/60 seconds off "
- 3 - 90 seconds on/60 seconds off "
- 4 - 90 seconds on/60 seconds off Remove mouthpiece, dispel saliva

The light would be on for a total of 6 minutes. The 60 seconds off in between prevents heat building up and maintains the lifetime of the LED's

REMOVE MOUTHPIECE, ALLOW CLIENT TO DISPEL SALIVA INTO 2 PAPER TOWELS, INSTRUCTING TO REMOVE THE DISPOSABLE MOUTHCOVER AND SHADE THE TEETH. BEGIN THE SECOND 4 CYCLES SAME AS ABOVE. APPLY A CLEAN DISPOSABLE COVER, REAPPLY GEL TO THE CONCAVE OF THE MOUTHPIECE, INSERT AND RESET THE BLUE LED MOUTHPIECE LIGHT WITH THE RED BUTTON IN THE CENTER OF THE MACHINE.

Do not use air. Examine teeth and shade, apply fresh gel after each 4 cycle treatment.

IF THE TEETH ARE NOT WHITE ENOUGH REPEAT ABOVE (4) CYCLE TREATMENT CONSECUTIVELY UP TO ONE FULL HOUR. 4 TO 5 CYCLES MAY BE NEEDED FOR HARD TO WHTEN TEETH OR A RETURN VISIT MAY BE SUGGESTED.

When treatment is complete, document after shade on client/patient chart. Have

the patient/client swoosh for 30 seconds with **BriteWhite After Rinse** to

neutralize the teeth, alleviate discomfort caused by the whitening solution,

desensitizing the teeth, and preventing hypersensitivity to cold or hot. **SANITIZE**

WITH GERMICIDE, DENTAL ANTI-BACTERIAL CLEANSER WHEN WHITENING

TREATMENT IS COMPLETE.

Recommend THE HOME MAINTENANCE to the PATIENT/CLIENT. (MAKE COPIES FROM THE DIRECTIONS IN YOUR MANUAL) **SELL (1) ACTIVATING GEL, (1) SET OF THE TRAY AND CASE, (1) TOOTHPASTE AND (1) MOUTHRINSE.**

A return visit (after two weeks) may be suggested at this time. **Whitening Activator (Dual) should be stored** in a cool environment – out of direct heat or light. No display cases.

Recommend **BriteWhite Trays** using **BriteWhite Cleansing Gel** to prep for sensitivity only if needed – wear 15 minutes. Apply **BriteWhite Activator** in trays for boosting treatments – wearing trays with activator 30 -40 minutes for maintenance daily for the first **five - seven days** and as needed for those who smoke, drink coffee, etc. for maintenance.

The edges, or biting edges and sides of the teeth will whiten quicker than the rest of the teeth. The enamel is thicker; however, the color will eventually blend.

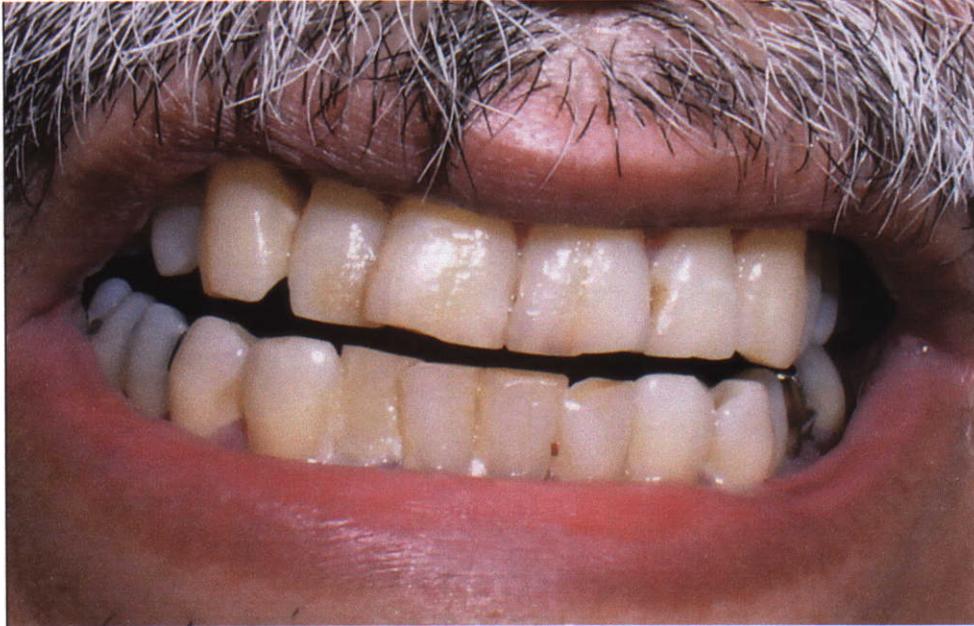
Tetracycline and teeth discolored from nicotine, coffee, colas, tobacco, red wine, some antibiotics, excessive fluoride, or from trauma may required a return treatment. If the patient complains of sensitivity discontinue treatment. Use Post Treatment Protocol and have the patient return after two weeks to continue the whitening process, using Post Treatment until the next follow-up chair side treatment.

Exceeding the recommended exposure time can result in penetration of the activator to the pulp chamber, causing sensitivity. Remember, if any patient reports burning or severe tooth sensitivity, the procedure should be terminated, and whitening activator removed. **Protective** neutralizes blanched areas. For **burning (blanching)**, rinse with cold water and reapply **BriteWhite**

Protective, Dual Activator and treatment can resume.

NOTE: *Because adolescents having large pulp chambers, it is advisable to perform only 2 applications if the patients/clients start to report sensitivity.* Shade improvement may develop for up to 8 hours. The patient should avoid tobacco, wine, and any teeth discoloring foods and beverages, through a straw, for at least 48 hours after the treatment. The teeth are vulnerable during this time period.

Hard to whiten teeth



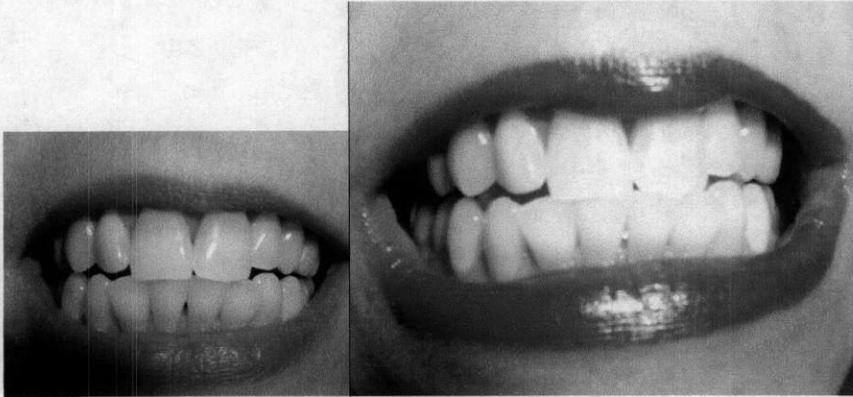
Before and after one single 15 minute treatment without removing tartar and plaque.

Aged teeth sometimes whiten very quickly as seen below.



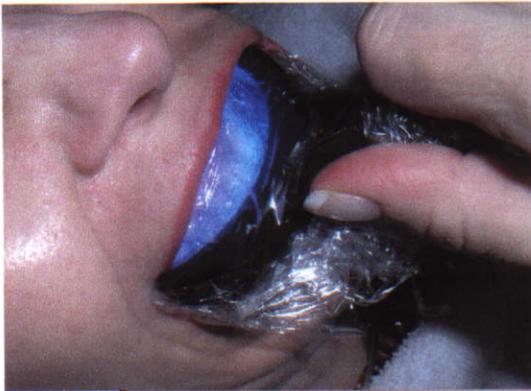
Aged

Teeth Very Yellow – 11 shades whiter in 12 minutes.



This Tetracycline patient

had Zoom whitening prior to using **BriteWhite**. Notice her teeth still looked discolored. She complained with being very sensitive from the Zoom treatment to both teeth and gingival up to two weeks after. She had one 15 minute treatment with **BriteWhite**. Her teeth are noticeably much whiter and with no sensitivity. **Uneven Bleaching:** Some patients will experience a temporary mottling of the teeth, because some areas of the teeth will whiten quicker. This will always settle down over time as treatment continues. When problems with gum recession have occurred, this root area where gum recession has occurred is not covered by enamel, but composed of dentin. This darker portion of the root of the tooth will not change noticeably as a result of the bleaching efforts.



Simple and easy to use application for the **BriteWhite Teeth Whitening Systemtm**.

TREATMENT PROTOCOL/Red LED Mouthpiece Optional Detachable Mouthpiece

Using the **BriteWhite** Red LED Light Therapy is intended to emit light generally indicated, to provide topical heating to promote increased blood flow, the temporary relief of minor muscle and joint pain, relieving stiffness and promoting relaxation of muscle tissue. No reported damage to healthy tissue or side effects has been documented. Red light has been used to stimulate cellular reproduction, speeding up the healing process by carrying more oxygen and nutrients needed for healing. Edema (liquid and protein) can be evacuated at a much faster rate to relieve swelling when treating the area with Red Light Therapy. The photons of light energy reduce the nervous tissue when the light enters the body as negative ions. The body sends positive ions to the area being treated, assisting in the firing of the nerves and relieving pain. Stimulating the fibroblastic activity aids in the repair process. This stimulation process is part of the process for healing inflamed tissue, wounds, and ulcers of the mouth and produces collagen which is the most important component for wound healing.

When using the **BriteWhite** Red LED Light's non-coherent attachment promotes the demineralization of bone tissue, regeneration of skin and blood tissue in that area.

The selected wavelength (600 nanometer spectrum) works because it is closer to the resonant frequency of cell tissue and absorbs better in hemoglobin. When using the Red LED Light attachment, sanitize the area being treated. Apply the **BriteWhite** Red LED Light attachment to the area for fifteen (15) to twenty (20) minutes.

The cell is in control of the treatment, shutting off the molecules when done making it impossible to overuse the light. The Red LED Light has longer wavelengths than the Blue LED Light allowing it to penetrate tissue more deeply boosting healing. Proper treatment can help fight gum disease. With the use of Blue LED Light, research theory believes that it can prevent and treat for control, periodontal disease. The following research taken in part:

Main Category: Dentistry News

Article Date: 01 Apr 2005 - 0:00am (PDT) Blue light fights gum disease culprits, Forsyth scientists find

Boston—Scientists at The Forsyth Institute have found that blue light can be used to selectively suppress certain bacteria commonly associated with destructive gum disease.

The research, published in the April Journal of Antimicrobial Agents and Chemotherapy, suggests that light in the blue region of the visible spectrum might be useful in preventing, controlling or treating periodontitis -- an oral infection that can lead to loss of bone and teeth.

Among the more destructive bacteria are the so-called "black-pigmented bacteria" (BPB) which have been implicated as pathogens associated with periodontitis. Such bacteria accumulate black pigment consisting mainly of organic compounds called porphyrins. Some porphyrins are photosensitive, and, when activated by visible light, induce a photodynamic reaction that kills the microorganism within seconds.

The Forsyth team also knew, from published reports, that porphyrins absorb blue light more readily than light that is red or green.

They found that the light rapidly killed BPB in pure cultures and that it selectively eliminated BPB in plaque samples containing 500-600 different bacteria. They also found that certain species were more readily inactivated by the light than others and that varying the intensity and exposure time had different impacts on different species.

The researchers conclude that intraoral light exposure can selectively reduce pathogens in dental plaque.

If proved effective in clinical studies, the findings could lead to new methods for preventing or controlling periodontal disease. Such methods would be rapid, non-invasive, and nontoxic. The Forsyth Institute is an independent, non-profit research organization focused on oral,

craniofacial and related biomedical science

SUMMARY

Now that you have completed your whitening treatments, make sure your patient understands the importance to care for his/her new **BriteWhite** teeth. This new technology will bring you high revenue returns plus boost your retail with a complete **BriteWhite** Home Care Kit for maintaining white teeth.

The degree of lightening depends on many factors:

- Age
- Certain antibiotics, such as Tetracycline, etc.
- Illness
- Discolorations from foods and beverages. **The first 72 hours is the most critical period.**

How long will your whitening last?

Depends on whether you use the maintenance suggested, eat, drink or use nicotine, color related foods or beverages. Touch ups are recommended once yearly.

Activating Gel

Some of you have addressed questions regarding the gel used with the BriteWhite

Teeth Whitening System™. Please note the following for your file:

There are many formulations of gel on the internet to choose from; however, during the six (6) year development of BriteWhite, many strengths were used in clinical studies. We did 100's of clinical studies. To explain the difference in whitening gels, BW gel is offered in a dual syringe, with 16% and water catalysts to control the loss of water preventing dehydration. The teeth do not become sensitive and no loss of calcium or softening of the enamel has been documented. Using other bleaching gels will void the warranty of your BriteWhite and could cause damage to the mouthpiece, preventing the light from producing satisfactory results. The dual activator is tailored to work with the selected wavelength (without heat) for the mouthpiece to prevent damage. The Activating Gel is patent protected both US and internationally and cannot be bought on the internet. BriteWhite has Global Patent Pending with Trademark protection.

The system was developed for the best results without the fear of sensitivity and loss of enamel. Protocol for whitening uses 1/2 the amount other systems require, keeping cost low and revenue return high.

Strengths of 35% Carbamide Peroxide or high Hydrogen Peroxide strengths can cause extreme sensitivity to the gums and teeth, or damage the enamel.

Direct quote from: " American Dental Association spokesman David Sarrett, DMD, a professor of dentistry at Virginia Commonwealth University:

Since they are considered "cosmetic" products, tooth whiteners don't fall under FDA regulation. While dentists have used these gels for some time, commercially available products have only been available for several years, so their long-term effects haven't been studied.

Studies show that often less than 50% of the whitener is still in the trays one hour after application, indicating a lot of leakage. **Sarrett does caution against buying tooth whitening products over the Internet -- for another reason. "They may have the right ingredients, but because they don't balance ingredients properly, they may not have the right pH, as with gels used by dentists or from reputable companies," he says. "It could be too acidic, which we know can damage tooth enamel."**

Keeping this in mind, BriteWhite has the lowest pH balanced whitening activator. Our interest is for the safety of those using both the activator, cleansing gel and mouthwash.

The mixed gel has a non-acidic pH and therefore does not have the potential to cause the damage to teeth enamel commonly associated with most whiteners which have an acidic pH.

GLOSSARY

Abrasives: Ingredients which help to get rid of unwanted discolorations, plaque and tartar.

Active Ingredients: Ingredients that chemically affect teeth and gums. These ingredients help improve the teeth and are healthy for the gums.

Arches: All teeth on the upper or lower jaw.

Bleaching: A chemical solution using gel or bleaching agents such as hydrogen peroxide, carbamide peroxide or special custom blends used to whiten teeth.

Boil & Bite Trays: Moldable mouthpieces used for holding the whitening agents to maintain white teeth at home. They are dipped into hot water for molding the form to the teeth for the upper and lower arch.

Chair side bleaching: Professional teeth whitening services performed under professional assistance.

Desensitizing: Substances used to reduce tooth pain after whitening or bleaching. They help to block microscopic holes in teeth that can cause pain.

Gingiva: A technical term for the tissue that covers the jawbones, known as the “gums.”

Hypersensitivity: A word that describes a condition where pain is caused by actions normally not troublesome.

Labial: The area in the mouth around the inside of the lips.

Laser Bleaching: An expensive form of teeth whitening performed only by dentist and usually causes extreme sensitivity to the gums and teeth.

LED Light Emitting Diode: A blue LED Light with a specific wavelength used to activate the gel attacking the discolorations without affecting the teeth, pulp or harming the gums. This form of whitening teeth is known to kill bacteria, strengthen the gums, non-invasive and without heat. Red LED Light in the 600 nanometer spectrum is generally indicated for the treatment of periobital wrinkles and rhytides, to provide topical heating to promote increased blood flow, relaxation of muscle and relief of joint pain.

Low Lip Line: When the widest part of the smile will only reveal the lower edges of your upper front teeth.

Mandible: The lower jaw.

Maxilla: The upper jaw.

Molars: The twelve broad back teeth, three on each side of the upper and lower dental arches.

Occlusion: How the teeth of the upper and lower jaws fit against one another when the jaw is closed.

Oral Hygiene: Brushing teeth regularly after meals to reduce discolorations.

Permanent Teeth: Thirty two teeth in an adult.

Plaque: A mixture of food particles, bacteria, and bacterial deposit that form into a substance creating a dirty, nasty film on the teeth.

Porcelain: A ceramic material, fired in an oven at a very high temperature to form a tough durable enamel substitute for covering problem teeth.

Porcelain Veneers: Thin layers of shiny white porcelain made to size in a laboratory, fixed to the front of a tooth for aesthetic purposes to improve color and shape.

Posterior: The teeth towards the back of the mouth. They are not usually visible when one smiles. Whitening these teeth is usually not necessary.

Preservatives: Allows for a longer shelf life.

Pulp: All of the nerves, blood vessels and connective tissues that exist inside each individual tooth.

Pulp Cavity: The pulp cavity is the inner space of the crown and the root where the pulp is contained in a tooth.

Root: The structure made from dentin and covered with cementum below the crown that anchors every tooth to the upper or lower jawbone

Root Canal: The area of the pulp cavity inside the root.

Saliva: Clear fluid used to aid chewing in the mouth and contains water, mucus and enzymes, but also bacteria.

Strips: Products like Crest White strips that only whiten the front and not the cracks of the teeth, leaving noticeable crevices and cracks discolored.

Syringes: Plastic nozzles used to place the bleaching or whitening agents in the mouth trays or onto the teeth prior to teeth whitening treatments.

Tartar: Yellowish brown material that sticks to the teeth and causes discolorations, often referred to as "calculus." It is also hardened plaque that was not properly removed by brushing or flossing. Cigarettes cause heavy tartar buildup.

Recommend **BriteWhite** After Care For Home Maintenance

STAY WHITE WITH.....

BriteWhite TEETH WHITENING

SYSTEM_{tm}

A cool way to whiten teeth.....

BEKS Incorporated

— 401 14th Avenue N.E., Jasper, AL 35504
Toll Free 888/582-3650 – Direct 205/384-3640
Fax 205/384-3910
Email: Customerservice@britewhitesystem.com
www.britewhitesystem.com



BRITEWHITE

TEETH WHITENING SYSTEM™



A **NEW** concept for Professional Teeth Whitening
using Blue LED, Light Emitting Diode

BriteWhite offers the first LED Light Emitting Diode system that is inserted "inside the mouth" for the ultimate in professional teeth whitening. BriteWhite treats all of the teeth (front, back and gums). Results for whitening teeth are obtained by attacking the discoloration of the teeth. A specially tailored gel, a specific wavelength and power are combined to boost the delivery of the light and to all teeth.

BLUE for Whitening Teeth RED for relief of pain all in one unit



Benefits

Blue

- No Sensitivity For Most
- No Gagging
- No Long Waiting
- No Saliva Drips
- No Heat
- No Rubber Dams
- No Check Retractors
- User Friendly
- 6 to 11 shades lighter in less than 20 minutes

Red

- Promotes Increased Blood Flow
- Temporary Relief of Minor Muscle & Joint Pain
- Relieves Stiffness and promotes relaxation of the muscle tissue

BRITEWHITE Teeth Whitening System
www.britewhitesystem.com

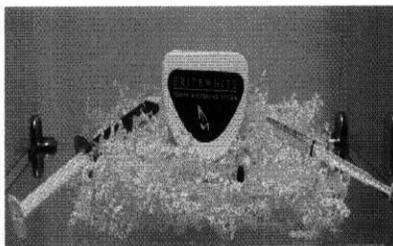
Patents Pending



Professional Teeth Whitening

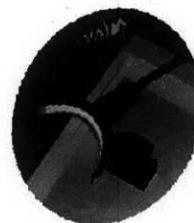
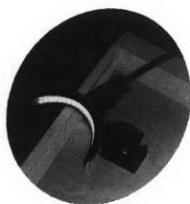
Now Available for Salons, Spas and MedSpas

- ***Low Investment, with High Returns***
- ***Chair Side Procedure***
- ***Blue and Red LED Technology***
- ***Portable***
- ***Repeat Consumables Income***



BriteWhite whitens the teeth, removes years of discoloration without softening enamel, causing corrosive problems, or disrupting the soft and hard tissue.

A revolutionary technology to lighten teeth 6 to 11 shades in less than 20 minutes without sensitivity



1-Year Parts & Labor Warranty
Made in the USA
Patents Pending

BriteWhite Teeth Whitening System
BEKS Incorporated
Toll Free (888) 582-3650
www.britewhitesystem.com

HOW OFTEN DO I NEED BriteWhite TREATMENTS?

Most professional teeth whitening treatments last up to one year. Some have boosting treatments within the first six months after the initial whitening.

WHAT CAUSES TEETH STAINS?

Stains are caused by many factors, aging, Red Wine, cigarettes, coffee, tea, blueberries, antibiotics and illness.

Benefits Include:
No Sensitivity For Most
No Gagging
No Long Waiting
No Saliva Drips
No Heat
No Rubber Dams
No Cheek Retractors
User Friendly
Used **ONLY** in the Professional Use Only

WHAT IS BriteWhite LED LIGHT?

BriteWhite Teeth Whitening's special blend activator is applied directly to the teeth. The mouthplate uses an array of Blue LED lights inside the mouth and directly to the teeth attacking stains without heat or damage to the pulp or softening the enamel.

The newest teeth whitening system for brighter and whiter teeth

A Winning

Smile everytime.....

HOW DOES BriteWhite WORK?

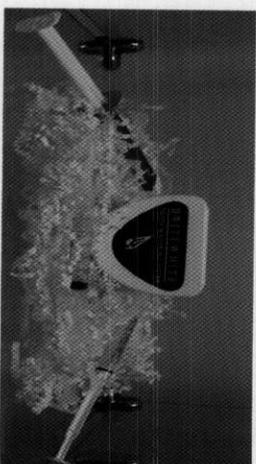
A special blend of BriteWhite gel is applied generously to the teeth. The Blue LED light is inserted inside the mouth. The teeth whiten within minutes.

WHERE CAN I GET MY TEETH WHITTENED?

BriteWhite Teeth Whitening is offered under professional technology. Contact your nearest BriteWhite Clinic.

CAN I CONTINUE TO USE MY CUSTOM TRAY?

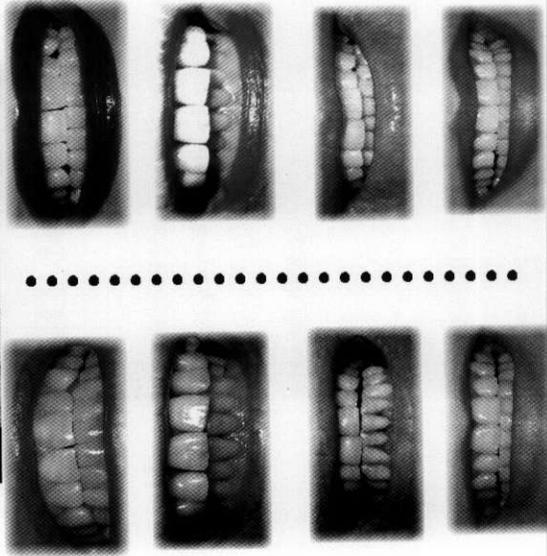
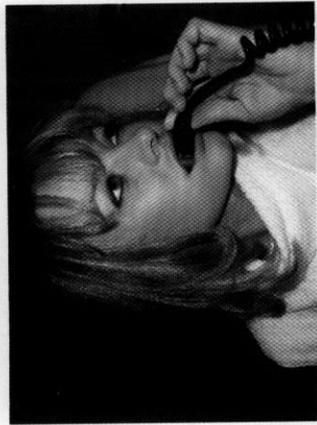
Yes, plus boil and bite trays will be available to purchase for keeping teeth white. BriteWhite offers a retail special blend gel for purchasing with the trays.



Contact your nearest
BriteWhite Clinic

BriteWhite

is the first professional teeth whitening device offered in both the medical and esthetic industry. The cutting edge for teeth whitening.



A NEW concept for Professional Teeth Whitening using Cool Blue LED Light Emitting Diode activating the dual action gel attacking the stains only quickly and safely.....

94

BriteWhite uses an array of Blue LED Light that can lighten your teeth:

- SAFELY
- QUICKLY
- AFFORDABLE

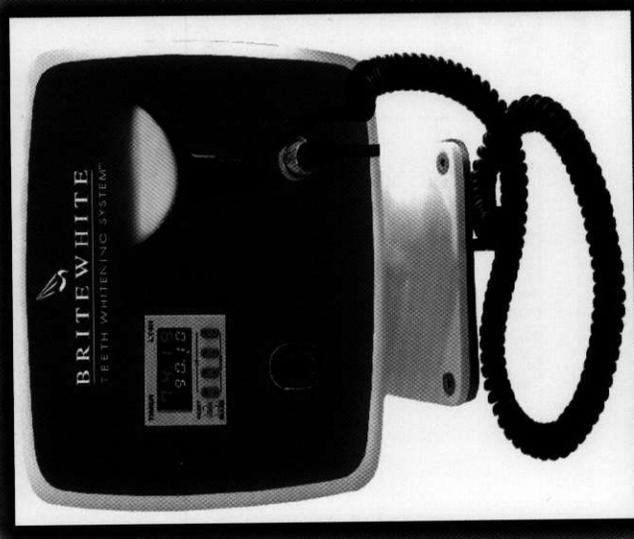
BriteWhite whitens the teeth, removes years of stain without softening enamel, causing corrosive problems, or disrupting the soft and hard tissues.

A revolutionary technology to lighten teeth 6 to 11 shades in less than 20 minutes without sensitivity.

BriteWhite Teeth Whitening System[™]

Contact Your Local Distributor

Global Patent Pending
BEKS Incorporated



Be On The Cutting Edge With.....



BRITEWHITE
TEETH WHITENING SYSTEM[™]

From: Reviewer(s) - Name(s) Michael E. Adjei
Subject: 510(k) Number K063704 / S1
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

572.6475, EEG II

Review: [Signature] (Branch Chief) DE03 (Branch Code) 2/28/07 (Date)

Final Review: [Signature] (Division Director) 2/20/07 (Date)

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K063704

Reviewer: Michael E. Adjodha
 Division/Branch: DAGID/DEDB
 Device Name: *BriteWhite Teeth Whitening System*
 Product to Which Compared (510(K) Number If Known):
QuickSmile (K052040)
Sonx 35 Ultrasonic Bleaching System (K041392)

	YES	NO	
1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?		X ¹	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	X ²		If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		X ³	If YES = Stop NE
9. Accepted Scientific Methods Exist?	X		If NO = Stop NE
10. Performance Data Available?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X ⁴		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

¹ Change in energy source

² Safety and effectiveness of the procedure may be affected by energy source

³ This energy source is well characterized

⁴ Engineering performance data show the device emits energy similar to other LED activation units.

1. Intended Use: *BriteWhite Teeth Whitening System*, a light source for tooth whitening, is intended to provide blue light for activation of gels used in tooth whitening procedures.
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

See Attached Review Memorandum.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication?
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION



REVIEW MEMORANDUM

Date: 16 February 2007

From: Michael E. Adjodha, Chemical Engineer, DAGID, HFZ-480

Subject: *BriteWhite Teeth Whitening System* (K063704)
BEKS, Inc., Jasper, AL

To: The record

Contact: Ms. Jill Creasy, Phone: 630-480-0476

I. BACKGROUND

BEKS, Inc., of Jasper, AL, has submitted a Premarket Notification to introduce into U.S. interstate commerce, *BriteWhite Teeth Whitening System*, a light source for tooth whitening. *BriteWhite Teeth Whitening System*, a prescription Class I exempt medical device, is classified as a "heat source for bleaching teeth" under 21 CFR 872.6475. *BriteWhite Teeth Whitening System* is not exempt from Premarket Notification because of a change in technology.

BriteWhite Teeth Whitening System is intended to provide blue light for activation of gels used in tooth whitening procedures.

BriteWhite Teeth Whitening System [redacted] (b)(4) system consisting of a base unit, an attached mouth piece, and disposable barrier sleeves. The device is intended to activate bleaching gels for cosmetic whitening of the teeth. [redacted] Product Specs

II. SUBMISSION CHANGES

By [redacted] (b)(4), the reviewer requested labeling changes and additional information on the technical specifications of the device. The submitter responded by a letter received on [redacted] (b)(4) Product Specs [redacted]

III. SUBMISSION SUMMARY

The light source for *BriteWhite Teeth Whitening System* device consists of [redacted] (b)(4) [redacted] (b) *BriteWhite Teeth Whitening System* employs a [redacted] (b) [redacted] (b) [redacted] (4) Pro

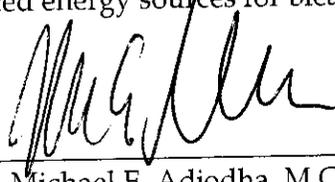
The specifications of the *BriteWhite Teeth Whitening System* [redacted] (b)

BriteWhite Teeth Whitening System, K063704, BEKS, Inc.

V. RECOMMENDATION

The information submitted by BEKS, Inc., demonstrates that *BriteWhite Teeth Whitening System* (K052040) has the same indications as a legally marketed device, has data establishing that the device is as safe and effective as a legally marketed device, and does not raise new types of safety and effectiveness questions. *BriteWhite Teeth Whitening System* is substantially equivalent (SE) to legally-marketed energy sources for bleaching teeth.

Primary Reviewer:



Michael E. Adjodha, M.ChE.
Chemical Engineer

Supervisory Reviewer:

Concur Do Not Concur
M. Susan Runner, DDS, MA
Chief, Dental Devices Branch

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

From: Reviewer(s) - Name(s) Michael E. Adjodha
Subject: 510(k) Number K 063704

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

*Telephone Hold
See fax*

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) _____

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

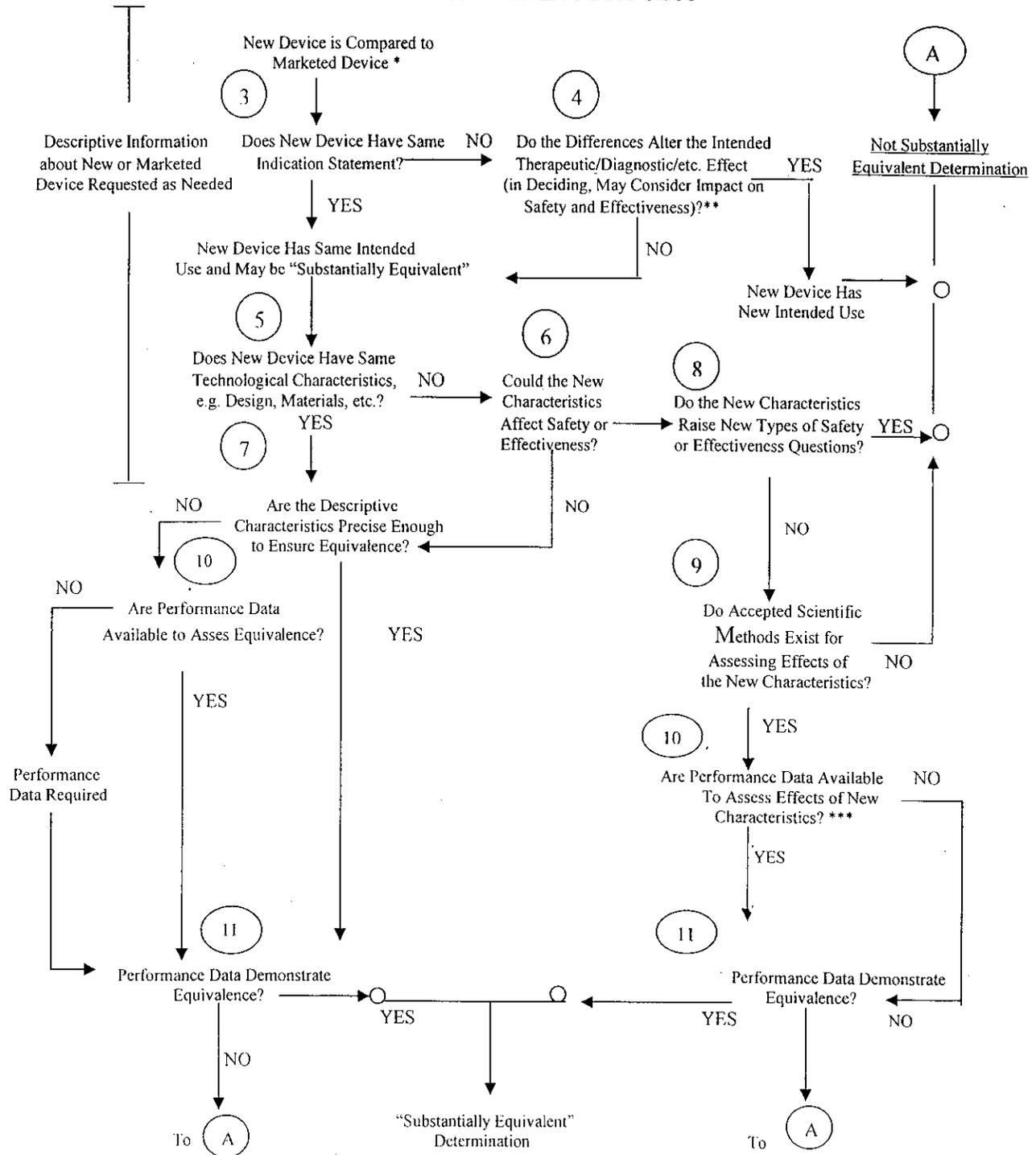
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: [Signature] (Branch Chief) 0503 (Branch Code) 1/29/07 (Date)

Final Review: [Signature] (Division Director) 1/29/07 (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DHHS/Food & Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard, HFZ-401
Rockville, MD 20850
Phone: 240-276-3688
240-276-3789



U.S. Department of Health and Human Services

Food and Drug Administration

FACSIMILE*

To: Ms. Jill Creasy

From: Michael E. Adjodha *MEU*

Fax: 630-665-3611

Pages: 1 (inc. cover)

Email: jcconsulting@comcast.net

Date: 1/29/2007

Re: Additional Information for **BriteWhite Teeth Whitening System** **CC:**
(K063704)

Urgent **For Review** **Please Comment** **Please Reply** **Please Recycle**

Dear Ms. Creasy,

Order to continue review of your 510(k) for **BriteWhite Teeth Whitening System (K063704)** and to establish substantial equivalence to legally marketed devices the following information and/or changes are requested:

Performance Specifications: (see the guidance for more information)

- Peak wavelength and range (nm).
- Number and type of LEDs
- Light intensity (mW/cm^2)
- Evidence of conformance to electrical safety and EMI standards.

Labeling:

• (b)(4)

• (b)(4)

Please fax (or email) your **complete** response to **Michael Adjodha (240-276-3789)** and mail a hard copy to the **Document Mail Center** at the address above. **Your document will be placed on hold. Incomplete responses will not remove the hold status.** Review of your application will resume once a complete response to the above information has been submitted. Please call me at **240-276-3688** if you have any questions. Thank you.

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on content of the communication is not authorized. IF YOU RECEIVED THIS DOCUMENT IN ERROR, PLEASE IMMEDIATELY NOTIFY US BY PHONE AND RETURN IT TO US BY MAIL AT THE ABOVE ADDRESS. Thank you.

Adjodha, Michael E

To: jcoconsulting@comcast.net
Subject: Additional Information for K063704

Importance: High
Sensitivity: Confidential

Attachments: Fax Coversheet--Labeling.doc; Indications for Use.doc; 1591.pdf

Dear Ms. Creasy

As we discussed in our telephone conversation today. Please see the attached information request as well as the format for Indications for Use . I am also including a relevant guidance document for reference. Please contact me if you have any questions.



Fax
Coversheet--Labeling.doc



Indications for Use.doc (32 KB...)
1591.pdf (112 KB)

Michael E. Adjodha

Michael E. Adjodha
Chemical Engineer
Dental Devices Branch
DHHS/FDA/CDRH/ODE/DAGID
Mail Stop: HFZ-480
Rockville, MD 20850
Room: 9200 Corp., 330L
Phone: 240-276-3688
Fax: 240-276-3789
E-mail: michael.adjodha@fda.hhs.gov

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		✓
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		✓

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K063704

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

- * - May not be applicable for Special 510(k)s.
- ** - Required for Class III devices, only.
- *** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard , which is posted with the 510(k) boilers on the H drive .]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No

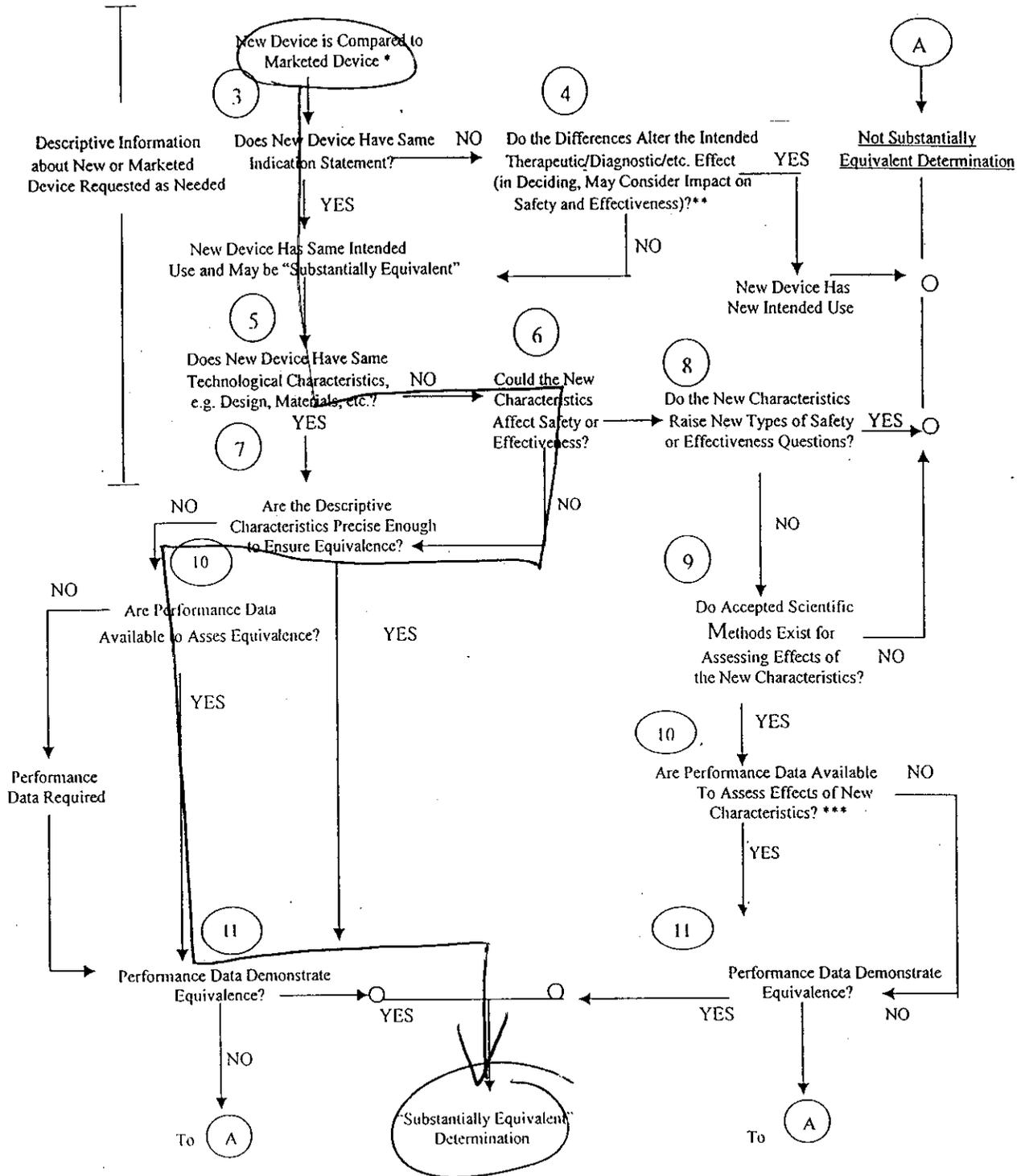
Reviewer: _____

Concurrence by Review Branch: _____

Date: DEC 14 2006

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 05, 2007

BEKS INCORPORATED
C/O JC CONSULTING
694 BLUFF STREET # 104
CAROL STREAM, IL 60188
ATTN: JILL CREASY

510(k) Number: K063704
Product: BRITEWHITE TEETH
WHITENING
SYSTEM, MODEL
BW1101

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K063704/S1



DHHS/Food & Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard, HFZ-401
Rockville, MD 20850

Ref: BriteWhite Teeth Whitening System (K063704)

Dear Michael Adjodha;

This letter is to inform FDA that BEKS Incorporated, removed all references in the indications, labeling, directions for use and summary referring to the (b)(4)



Submitter

Joyce Osborn
President/Developer
BEKS Incorporated
888-582-3650

Contact Person

Jill Creasy
JC Consulting
630-480-0476
jcconsulting@comcast.net

K54

RECEIVED
FBI
MAY 11 2011
11:46 AM

**FDA 510K Summary of Safety and Effectiveness for
BriteWhite Teeth Whitening System Professional**

1. General Information

Submitter: BEKS Incorporate
401 14th Avenue NE Unit #2
Jasper, AL 35501
888-582-3650
205-384-3940 Fax

Contact Person: Jill Creasy
JC Consulting
694 Bluff St. #104
Carol Stream, IL 60188
630-480-0476
jcconsulting@comcast.net

Summary Preparation Date: December 3, 2006

2. Device Name

Proprietary Name: BriteWhite Teeth Whitening System (Professional)

Classification Name: Light source for bleaching teeth (21 CFR 872.6475).

3. Predicate Device

The BriteWhite Teeth Whitening System Professional is substantially equivalent in respect to the intended use, design and method of operation to numerous cleared devices, including; the South Beach Smile Light Whitening System (K042153), QuickSmile (K052040).

4. Device Description

The BriteWhite Teeth Whitening System device that utilizes Light Emitting Diodes to provide a tooth whitening system, the whitening light source is a mouth piece which is placed inside the mouth, using barrier sleeves, which emits a biologically safe and effective level of blue visible light. The general wavelength for the mouth piece is 400 nanometer spectrums to provide a selected wavelength which activates the whitening gel to bleach the teeth without the aide of heat. To ensure user safety when operating the light, the system has a built in feature to eliminate any risk for the end user and professional. The light automatically shuts off after a specified period of time. Secondly, the light source in placed inside the mouth, so there is no need for safety glasses for the patient and professional. No contact with the eyes is in this area of treatment and prevents penetrations of blue wavelength and protects the vision of the patient and professional.

5. Indications for Use:

1. The BriteWhite Teeth Whitening System is intended to emit light in the 400 nanometer spectrums to provide a light source for bleaching of teeth.

6. Technical Characteristics

The BriteWhite Teeth Whitening System and the aforementioned predicate devices are the light source for bleaching teeth as defined in 21 CFR 898.6475.

The BriteWhite Teeth Whitening System is an economical tooth whitening light which in conjunction with the whitening gel and tooth whitening preconditioning mouth wash provides a light source for bleaching the teeth. The BriteWhite Teeth Whitening System has similar intended use and technological characteristics to the predicate devices. The primary difference is the BriteWhite Teeth Whitening System uses an inside the mouth, hand piece.

7. Conclusions

The BEKS Inc. BriteWhite Teeth Whitening System has the same intended use, with similar functional and performance characteristics. The BEKS Inc. BriteWhite Teeth Whitening System performs as intended and does not raise any new safety or efficacy issues.



BRITEWHITE

TEETH WHITENING SYSTEM™

A GOOD NEW WAY TO WHITEN TEETH...

LED Light Emitting Diode's
Blue LED Light For Whitening Teeth

**TEETH WHITENING
TREATMENT MANUAL**

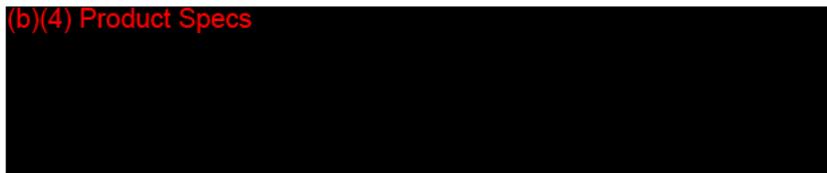
BEKS Incorporated — 401 14th Avenue N.E., Unit #2, Jasper, AL 35504
Toll free 88/582-3650 — Direct 205/384-3640 — Fax 205/384-3910 —
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117

Specifications

LED'S – Light Emitting Diodes

(b)(4) Product Specs



Power Supply

(b)(4) Product Specs

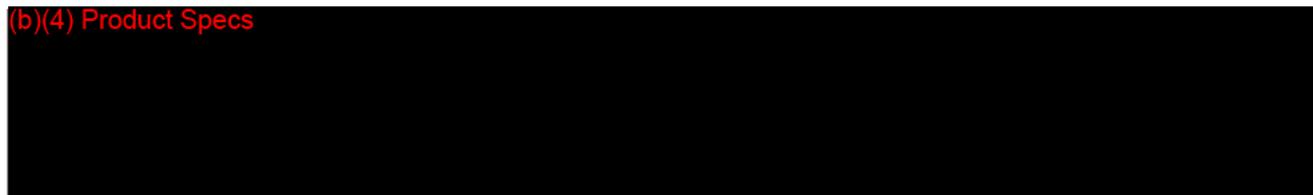


Treatment Timer

(b)(4)



(b)(4) Product Specs



Dimensions

(b)(4) Product Specs



Disposable Mouth Covers (Barrier Sleeve)

These disposable mouth piece protectors, slip over the mouth piece to protect it from products used during the treatments. One slip per treatment per client.

INDICATIONS FOR USE

BriteWhite Teeth Whitening System™ is intended to emit in the 400 nanometer spectrum to provide a light source for the bleaching of teeth.

Benefits of LED (Light Emitting Diode):

Longer life span

No need for filters

No need for cooling fan

No decrease of light output over the life time of the light device

No disruptive of soft and hard tissues

Takes less time for whitening without softening enamel or causing corrosive problems.

BriteWhite Teeth Whitening System will bring higher revenue returns.

Comfort for client/patient:

- Gingival Protection is Optional
- No Patient Sensitivity (most) New improved LED light is used for fast and effective whitening
- Non-Laser whitening procedure
- No long waiting
- No gagging
- No saliva drips
- No softening of enamel
- No Protective Eyewear needed.

Directions for use

- 1 – Fill out the Consent Form
- 2 - Shade the Teeth charting the shade
Instruct client/patient to remove discolorations if necessary with tartar tool (add on service)
- 3 – Ask patient/client to gently blot the teeth and gingiva
- 4 - Put a Disposable Cover (Barrier Sleeve) on the mouthpiece, molding it to the concave of the mouthpiece and twisting to hold in place. Direct the patient/client how to apply gel and insert the mouthpiece into the mouth.
- 5 – **DO NOT APPLY THE ACTIVATING GEL DIRECTLY TO THE TEETH.** Apply the Activating Gel directly to the center of the LED tip to tip lights (the concave part of the Mouthpiece). Instruct the patient/client to insert the mouthpiece in the mouth - starting at the corner at an angle and placing it directly against the teeth. Holding the other side of the mouth open helps place the mouthpiece correctly and directly against the teeth.
- 7 - Turn on machine. It auto counts 90 seconds at which time it shuts off the "Blue" LED light. **It does not shut off the machine.**

The first cycle would be:

- | | |
|----------------------------------|----------------------------------|
| 1 - 90 seconds on/60 seconds off | DO NOT REMOVE MOUTHPIECE |
| 2 - 90 seconds on/60 seconds off | " |
| 3 - 90 seconds on/60 seconds off | " |
| 4 - 90 seconds on/60 seconds off | Remove mouthpiece, dispel saliva |

The light would be on for a total of 6 minutes. The 60 seconds off in between prevents heat building up and maintains the lifetime of the LED's

REMOVE MOUTHPIECE, ALLOW CLIENT TO DISPEL SALIVA INTO 2 PAPER TOWELS,
INSTRUCTING TO REMOVE THE DISPOSABLE MOUTHCOVER AND SHADE THE TEETH. BEGIN THE SECOND 4 CYCLES SAME AS ABOVE. APPLY A CLEAN DISPOSABLE COVER, REAPPLY GEL TO THE CONCAVE OF THE MOUTHPIECE, INSERT AND RESET THE BLUE LED MOUTHPIECE LIGHT WITH THE RED BUTTON IN THE CENTER OF THE MACHINE.

Do not use air. Examine teeth and shade, apply fresh gel after each 4 cycle treatment.

IF THE TEETH ARE NOT WHITE ENOUGH REPEAT ABOVE (4) CYCLE TREATMENT CONSECUTIVELY UP TO ONE FULL HOUR. 4 TO 5 CYCLES MAY BE NEEDED FOR HARD TO WHITEN TEETH OR A RETURN VISIT MAY BE SUGGESTED.

When treatment is complete, document after shade on client/patient chart. Have the patient/client swoosh for 30 seconds with **BriteWhite After Rinse** to neutralize the teeth, alleviate discomfort caused by the whitening solution, desensitizing the teeth, and preventing hypersensitivity to cold or hot. **SANITIZE WITH GERMICIDE, DENTAL ANTI-BACTERIAL CLEANSER WHEN WHITENING TREATMENT IS COMPLETE.**