Literature Review Report Tanda Blue Light LED Devices

	Name	Title
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Changes Control Table:

Ver.	Rev.	DR\ECO	Page / Chapter	Description of Change	Date
01	00	HU-DR-0103	All	Replaces 00243R00 and Update report from 2011 to 2012 (all)	Sept 2012
	01	HU-DR-323	All	Updated with Zap Power and new clinical summaries available	Dec 2013

Document Classification (Agile database)

CL	DHF	DHR	DMR	DP	EX	FR	GN	LG	MR	OP	QP	RD	ST	TF	QAN
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1. **Scope**
   This literature review pertains to similar products to the Tanda Clear+, Zap and Zap Power that are available for sale in EU, USA and Canada that have similar technology and indications/intended uses.

2. **Purpose**
   A literature review was conducted in order to support the safety and efficacy of the Tanda Clear+, Zap and Zap Power, which are medical devices used to treat mild to moderate forms of acne. Articles were selected based on a set of criteria to establish the relevancy to the family of blue light LED devices with respect to the technology, output parameters and indications for use.

3. **Applicable Documents**
   MEDDEV 2.7.1 (Rev 3) - Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies

4. **Data sources used**
   The application of LEDs for aesthetic procedures has been established as both safe and effective for many years. As such, the Company can survey various databases for information on similar devices to better understand the safety and efficacy of its own products. A literature review was conducted to specifically review the scientific knowledge published from clinical trials or scientific experiments that are relevant to the Clear+, Zap and Zap Power products.

5. **Search summary**
   A search was conducted to obtain publications, articles and information pertaining to competitive devices using the databases as provided in Table 1 below. The search was limited to the English language and covers the years 2000 to 2013. This time frame was selected to reflect both the established and current information as well as any new advances in scientific technology/information relevant to the Company's products. Serious adverse events reported as well as the results of clinical investigations or in vitro studies were screened.

Table 1: External Sources

Source name	Website/Access
US FDA MAUDE Data Base Manufacturers and Users facility Device Experience	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
TGA Australia Medical device incident reporting and investigation scheme (IRIS) - article index	http://www.tga.gov.au/hp/iris-articles-index.htm#a
MHRA UK – Medical device safety Alerts	http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/MedicalDeviceAlerts/Devicealerts/index.htm
Pubmed	www.pubmed.com

The literature search was performed by using, as keywords, the appropriate terms to identify all publications containing information on the performance and safety of the devices for the treatment of acne. The search criteria are provided in detail below.

6. Search Methodology

6.1 US FDA Data search methods

Predicate devices in the market with similar technologies and intended uses as compared to the Tanda Clear+, Zap Power and Zap devices were identified.US FDA MAUDE database was searched by entering each of the known predicate device names as shown in the table below under the “brand name” in the database search engine.

6.2 TGA and MHRA UK data search methods

The TGA and the MHRA databases containing adverse reports as well as alerts and recall information released by the regulatory authorities were screened based to identify competitor devices, intended use (acne) and technology (LED or Light Emitting Diodes).

6.3 Bibliographical data bases search methods

Bibliographical data bases were searched using appropriate terms as detailed in the table below:

Table 2: Bibliographical Search Engine Key Terms

Terms	Search Engine
Blue Light Acne Vulgaris	Pubmed
Blue Phototherapy Acne	Pubmed
Blue LED efficacy acne	Pubmed
Clinical study blue light acne	Pubmed
Light emitting diode therapy acne	Pubmed
Mild to moderate acne treatment blue light	Pubmed
Blue light safety acne vulgaris	Pubmed

7. Selection criteria

7.1 US FDA data selection

Information obtained in the various data bases was assessed to weight its relevancy to the device/technology in question. Data generated from the device in question or from a competitor’s device was the selection criteria used as a basis for the information to be included in this clinical evaluation report.

7.2 TGA and MHRA UK

Information obtained in the various data bases was assessed to weight its relevancy to the device/technology in question. Reports or collations of data related to the device in question or from a competitor’s device was the selection criteria used to collect and use the information.

7.3 Bibliographical data bases

Articles obtained through the Pubmed search were assessed to weigh their relevancy the Tanda Clear+ and Zap devices with respect to its technology as well as indications for use. In general, articles were initially excluded if they were not a clinical study, an animal study, not sourced from a peer reviewed journal article or a subject matter that is irrelevant.

The articles were scored based on the following method and criteria as described in the Table 3 below:

Table 3: Article Scoring Method

Suitability Criteria	Description	Grading System (Value)
Appropriate device	Was the data generated from a comparable device?	3 Actual device 2 Technologically Comparable device 1 Other device (comparable in intended use)
Appropriate device application	Was the device used for the same intended use (e.g., methods of deployment, application, etc.)?	3 Same use 2 Minor deviation 1 Major deviation
Appropriate patient group	Was the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)?	3 Applicable 2 Limited 1 Different population
Acceptable report/data collation (number of patients)	Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment?	3 High quality 2 Minor deficiencies 1 Insufficient information
Data source type	Was the design of the study appropriate?	3 Yes 2 Partially 1 No

Table 3: Article Scoring Method

Suitability Criteria	Description	Grading System (Value)
Outcome measures	Does the reported outcome reflect the intended performance of the device?	3 Yes 2 Partially 1 No
Follow-up	Is the duration of follow-up long enough to assess duration of treatment effects and identify complications?	3 Yes 2 Partially 1 No
Statistical significance	Has a statistical analysis of the data been provided and is it appropriate?	3 Yes 2 Partially 1 No
Clinical significance	Was the magnitude of the treatment effect observed clinically significant?	3 Yes 2 Partially 1 No

8. Results of Database and Literature Review

8.1 US FDA MAUDE Data Base

Table 4: US FDA MAUDE Data Base Search Results

Device Name	Manufacturer	Reported by the Manufacturer Yes or No	Technology	510(k)	Code	MDR #	Performance/Safety	Problem/Injury	Device related y/n	Remarks
Skin Perfecting Blue	Tria Beauty Inc.	Yes	LED	K090312	GEX	3122196	Safety	Darkened skin area	Yes	Customer reported using the tria blue light acne device to "spot treat" a problem area and subsequently developed a "darkened skin area
Baby Quasar	QUASAR BIO-TECH, INC	Yes	LED	K091467	ILY	1692102	Safety	Skin burn	Yes	Over use of the device- subject fell asleep with the device on and in contact with skin
OmniLux Blue	PHOTO THERAPEUTICS, INC	No	LED	K043329	GEX	1028481	Performance and Safety	Poor performance and scarring	Yes	Direct user complaint, no investigation by the Manufacturer available on report.
OmniLux Revive	PHOTO THERAPEUTICS, INC	No	LED	K062321	GEX	1028481				
Zeno Hot Spot	ZENO CORPORATION	Yes	Low Level Heat	K043377	GEX	2364665	Safety	Caused hard cysts following use	Yes	Direct user complaint that they sustained cysts that were hard and painful following the use of the device

Device Name	Manufacturer	Reported by the Manufacturer Yes or No	Technology	510(k)	Code	MDR #	Performance/Safety	Problem/Injury	Device related y/n	Remarks
Zeno Hot Spot	ZENO CORPORATION	No	Low Level Heat	K043377	GEX	2009069	Safety		Undetermined	The manufacturer was unable to retrieve the device for a full investigation

8.2 TGA Iris data base

No incidents pertaining to aesthetic medical devices were submitted to the TGA.

8.3 UK MHRA data base

No incidents pertaining to aesthetic medical devices were submitted to the MHRA.

8.4 Literature Review- Pubmed data base

Table 5: Summary of Pubmed Search

Terms	Search Engine	Number of Hits
Blue Light Acne Vulgaris	Pubmed	70
Blue Phototherapy Acne	Pubmed	67
Blue LED efficacy acne	Pubmed	13
Clinical study blue light acne	Pubmed	23
Light emitting diode therapy acne	Pubmed	21
Mild to moderate acne treatment blue light	Pubmed	20
Blue light safety acne vulgaris	Pubmed	12

Table 6: Summary of Articles Identified for Review:

#	Reference	Summary
1	Papageorgiou P., Katsambas A., Chu A., **Phototherapy with blue (415 nm) and red (660 nm) light in the treatment of acne vulgaris** British Journal of Dermatology. 2000; 142: 973-978. **Technology** Wavelength: 415 +/- 20 nm Source: LED Output: 4.23 mW/cm2	**Methods** • 27 patients (19 female and 8 male) treated with blue light only (1 of 4 groups) in a total of 107 subjects enrolled • Presenting with mild to moderate acne on face • Subjects assessed at 4, 8 and 12 weeks from the start of the study • Assessment based on the number of lesions and the severity by investigator and blinded evaluator • Overall treatment response was evaluated at the end of the study by both the investigator and subject • **Results** • 4 subjects in the blue light only treated group reported adverse reaction (including flare up, dryness and rashes) • Overall, investigators assessed that over 75% of subjects treated with blue light alon had mild to marked improvement with about 5% having complete clearance • The patients overall assessment was that 90% had some form of improvement. **Conclusion** • Mean improvement 45% in comedones and 63% in inflammatory lesions for blue light only treated group • The combination group (red and blue light) had the most significant improvements, suggesting a synergistic effect of combining these wavelengths for the treatment of acne

#	Reference	Summary
2	Kawada A, Aragane Y, Kameyama H, Sangen Y, Tezuka T. **Acne phototherapy with a high-intensity, enhanced, narrow-band, blue light source: an open study and in vitro investigation.** J Dermatolog Science. 2002: 30: 129-135. **Technology** Wavelength: 407-420 nm Source: 400 W Metal halide lamp Output: 90 mW/cm2 Spot size: 20 x 20 cm2	**Methods** • 30 patients in total (27 females; 3 males) • Presented with mild to moderate acne on the face and/or back and/or chest • Between 15-100 inflammatory lesions and/or between 15-100 non-inflammatory lesions and no more than 3 nodules • Refrain from any medication 4 weeks prior to the start of the study • Two treatments weekly for 5 weeks • Clinical assessment at 0, 1, 3 and 5 weeks and at 1 month follow up after final treatment • Investigator's global assessment (5 point system- worsened to improved) • Bacterial cultures analyzed and in vitro irradiation of samples from subjects **Results** • 26 subjects completed the study • Reported individual number of comedones, papules, pustules and combined number of lesions altogether at 1, 3 and 5 weeks post treatment • Reduction of the number of lesions in % for comedones, papules, and pustules at combined lesion reduction at week 5 was: 57.8, 69.3, 73.3 and 64% respectively • At week 5, 77% of subjects were assessed as "improved" while 10% demonstrated "unchanged" • By week 5, 40% of subjects had improvement or clearance of lesions • No adverse effects, but dryness of irradiated skin for 2 subjects reported during the study • In the isolated cultures, *P. acnes* strains identified and were irradiated thereafter. Demonstrated significant reduction in the number of bacterial cells following irradiation. **Conclusion** • Reduction of skin lesion was 51.2% and 64% at 3 and 5 weeks respectively • 77% subjects showed improvement by the 5th week following treatment (20% remained unchanged or worsened) • Long term durability of the treatment (up to 1 month with only 6% increase from 5 week measurement) • Blue light effect more substantial for inflammatory papules and pustules (69.3% and 73.3% reduction) compared to comedones (57.8% reduction), consistent with prior studies. • Explained by the antibacterial effect of the blue light- targets inflammatory lesions.
3	Elman M, Slatkine M, Harth Y **The effective**	**Methods**

#	Reference	Summary

	treatment of acne vulgaris by a high-intensity, narrow band 405-420 nm light source. J. Cosmetic & Laser Ther. 2003; 5:111-116
	
	Technology
	Wavelength: 405-420+/- 20 nm
	Source: Non-coherent light source
	Output: 50-200 mW/cm2
	Treatment fluence: 90 mW/cm2
		• Three study groups
		  ○ Split face dose response- 18 treatment fields (half faces)
		  ○ Full face- open trial and split face- 13 patients treated
		  ○ Double blinded self-controlled- 23 patients treated
		• Presenting with papulo-pustular acne
		• **Results**
		• Split face dose response
		  ○ 50% decrease in 83% of the treated areas
		  ○ Mean number of lesions was 21 before the treatment and 7 afterwards
		• Full face- open trial and split face- 13 patients treated
		  ○ After 4 weeks of treatment, average of 59% reduction in inflammatory lesions of the 10/13 patients that responded to treatment
		• Double blinded self-controlled- 23 patients treated
		  ○ Lesion reduction at 2, 4 and 8 weeks was 59%, 61% and 53% respectively
		  ○ 87% of the treated sides showed a greater than 20% reduction of inflammatory lesions
		• No adverse effects reported for all study participants
		Conclusion
		• 80% of subjects responded to treatment and there was a significant reduction in the inflammatory acne after 8 treatments only
		Safe effective treatment
		• Blue light is therapeutic for the treatment of acne

4	Omi T, Bjerring P, Sato S, Kawana S, Hankins R, Honda M. **420 nm intense continuous light therapy for acne.** J Cosmet Laser Ther. 2004; 6: 156-162.
	
	Technology
	Wavelength: 410-420 nm
	Source: Continuous wave of light emission
	Output: 200 mW/cm2
	Treatment: 15 minute exposure
		Methods
		• 28 patients in total
		• Acne graded (0-5) according to Burton et al scale
		  ○ Grade 0:no acne recognized
		  ○ Grade 1: mild comedos
		  ○ Grade 2: Comedos, small papules or small cysts
		  ○ Grade 3: moderate acne (between grades 2 and 4)
		  ○ Grade 4: apparent cyst formation
		  ○ Grade 5: large cyst or cystic formation accompanied by inflammation
		• Acne score based on Allen and Smith method.
		• # of lesions falling into each grade (0-5) was assessed pre- treatment, after 4 treatments and after 8th treatment.

#	Reference	Summary
		• Dermal moisture, sebum and pH level, blood flow measured prior to and 30 minutes following irradiation • Detection of bacteriological growth in acne lesions • Dermal biopsies taken and P acne bacteria on surface was assessed via PCR **Results** • No difference in acne grade distribution before and after treatment • 64.7% overall improvement and total number of acne lesions before and after treatment was significant in its reduction • 6 subjects sustained effectiveness post 2 months following last treatment • Only a reduction in skin's moisture, but no other difference in other skin attributes measure (prior and after irradiation) • *P acnes, S epidermidis and Enterobacteria* found in bacteriological investigation • Biopsies common finding was well developed sebaceous gland cell • No adverse events reported during the study **Conclusion** • Device is clinically effective in treatment of acne (via reduction in grade 3 and 4 acne lesions).
5	Tzung TY, Wu KH, Huang ML. **Blue light phototherapy in the treatment of acne.** Photodermatol Photoimmunol Photomed. 2004; 20: 266-269. **Technology** Wavelength: 420+/- 20 nm Source: LED Output: 40 J/cm2	**Methods** • 31 Taiwanese patients in total enrolled in the study • Presenting with mild to moderate acne on face • At random, only 1 side of the face received treatment • Treatment twice per week for 4 weeks • Clinical assessment performed during treatments and 1 month post last treatment • Acne scale described by Michaelsson et al use. Both the number and size of the acne lesions were assess and each type of lesion was assessed for its severity **Results** • 28 subjects completed the study (3 dropped) • Compared to non-irradiated side, there was significant improvement after 8 weeks • First sign of improvement after 4 weeks, mean improvement was 52% **Conclusion** • 52% mean improvement after a total of 320 J/cm2 of irradiation dose of blue light Papulopustular lesions responded to the blue light irradiation better than either comedones or nodulocysts

#	Reference	Summary
6	Morton CA, Scholefield RD, Whitehurst C, Birch J. **An open study to determine the efficacy of blue light in the treatment of mild to moderate acne.** J Dermatolog Treat. 2005;16(4):219-23 **Technology** Wavelength: 409-419 nm Source: LED Output: 40 mW/cm2 Treatment: 10 minutes (24 J/cm2) 20 minutes (48 J/cm2)	**Methods** • 30 patients in total (47% females; 53% males) • Presented with mild to moderate acne on the face based on Global Acne Grading System • 23 subjects received 20 minute treatments; 7 subjects received 10 minute treatments • Two treatments weekly (3-4 days apart) for 4 weeks for a total of 8 treatments • Clinical assessment at 0, 1, 4 and 8 weeks following final treatment with voluntary follow up 12 weeks post last treatment • Acne improvement and subject tolerance graded. **Results** • 28% of subjects had optimum clearance at 4 weeks (average clearance of 76%) • 55% and 17% reached optimum clearance at 8 and 12 weeks post treatment • Average reduction at 1, 4 and 8 weeks was 31%, 4% and 2% respectively • 75% subjects reported that they would use the treatment again • Minor adverse events reported include redness after treatment, dryness of skin and mild pruritis. **Conclusion** • Study demonstrated blue light therapy (409-419 nm) significantly reduces inflammatory acne lesions • Time to reach optimum clearance differed among subjects- indicating there may be other secondary mechanism of action involved in the therapeutic effect of destroying the acne bacteria Interestingly, the dosage differences did not impact the clinical effect between the two groups
7	Tremblay JF, Sire DJ, Lowe NJ, Moy RL. **Light-emitting diode 415 nm in the treatment of inflammatory acne: An open-label, multicentric, pilot investigation**. J Cosmet Laser Ther. 2006 Apr;8(1):31-3. **Technology** Wavelength: 415 nm Source: LED	**Methods** • 45 patients in total (31 female, 14 male) • Presenting with mild to moderate acne on face (exclusion nodulocystic acne • Received 2, 20 minute treatments per week for 4-8 weeks • Clinical assessment performed at 0, 2, 4, 8 weeks from the start of the study • 4 point scale- Global improvement scale used to assess improvement in acne: ○ 0- no improvement ○ 1- 0-25% ○ 2- 26-50% ○ 3- 51-75% ○ 4- 76-100% • Patient tolerance and satisfaction assessed as well

#	Reference	Summary
	Output: 48J/cm2 Treatment: 20 minute exposure	**Results** • 43 subjects completed the study (2 dropped) with no adverse events reported • Average improvement score was 3.14 and 2.9 after 4 and 8 weeks respectively • 9 subjects had complete resolution of their acne after 8 weeks • 50% were highly satisfied, 40% were mild to moderately satisfied and 10% were not satisfied • Subjects also report decrease in skin oiliness and pore size **Conclusion** LED blue light therapy a credible treatment modality for acne
8	Noborio R, Nishida E, Kurokawa M, Morita A. **A new targeted blue light phototherapy for the treatment of acne.** Photodermatol Photoimmunol Photomed. 2007; 23: 32-34. **Technology** Wavelength: 405-420 nm Source: High intensity, narrow band UV free light Spot size: 73 X 23 mm Treatment: 1 pulse is 6 J/cm2. About 6 pulses/area treated.	**Methods** • 10 Japanese patients in total (8 females; 2 males) • Presented with mild to moderate acne on the face or back • Acne score based on Allen and Smith method. • Treated 1 or 2 times per week until satisfactory results obtained • Two treatments weekly (3-4 days apart) for 4 weeks for a total of 8 treatments • Clinical assessment before and after last treatment based on the severity of the lesion (Allen and Smith score method) **Results** • 8 subjects completed the study and 2 dropped • No side effects reported • 80% of subjects showed improvement with an average of 12.4 treatments **Conclusion** • Potential of new device that targets specific areas rather than larger area treatments like its predicate device. • Safer for patient, less risk of ocular damage/injury
9	Ammad S, Gonzakes M, Edwards C, Finlay A, Mills C. **An assessment of the efficacy of blue light phototherapy in the treatment of acne vulgaris.** J Cosmetic Derm. 2008; 7:180-188 **Technology** Wavelength: 415-425 nm Source: 400W Metal halide lamp	**Methods** • 21 patients in total • Presenting with mild to moderate acne • Received 2, 14 min exposure per week for 4 weeks (8 treatments in total) • Assessments made using Leeds Acne Grading Scale and Leeds Counting technique at baseline and after 8th treatment • Dermatology Life Quality Index (DLQI) forms were completed by patients before and after the study • Visual analog scale scores were recorded by both patients and investigators

#	Reference	Summary
	Output: 70-90W/cm^2 Treatment: 14 min exposure	**Results** • 21 patients completed the study • In comparison between the assessment made at baseline and after 8th treatment, after 8th treatment the results showed: ○ Decrease in acne grade by 11.2% ○ Decrease in the average of inflamed lesions by 13.87% ○ Decrease in the average of non-inflammatory lesions by 10.23% ○ Decrease in average DLQI scores by 18.8% ○ Decrease in VAS by 10.8% - assessed by patients ○ Decrease in VAS by 10.6% - assessed by investigators **Conclusion** • Blue light phototherapy in the treatment of mild to moderate acne is effective
10	Sadick SS, Laver Z and Laver L. **Treatment of mild-to-moderate acne vulgaris using a combined light and heat energy device Home-use clinical study.** J Cosmetic and Laser Therapy 2010; 12: 276-283 **Technology** Wavelength: 450-2000 nm Source: Broad Spectrum Light and Heat (LHE) Spot Size: 3 cm x 5 cm Treatment: 6 J/cm2 per treatment cycle (2 passes per each treatment cycle). Twice per day for 4 days. 6-12 hours between each treatment.	**Methods** • 63subjects (46 females and 16 males)– 31 treatment group and 32 were part of placebo group • Presented with at least [illegible] inflamed papules on their face • Treatments were self administered, twice a day (6-12 hours between treatments) for 4 days. A treatment consisted of two passes with the device • Subjects evaluated by the blinded investigator as well as an independent blinded evaluator based on 4-point VASE scale as well as on a 5 grade photographic lesion reference scale (PLRS) for the assessment of the improvement per lesion. • Subjects were asked to keep a treatment diary to record any possible side effects and to assess their improvement using the VASE scale. • The unblinded observer in the study also assessed subject safety during office visits. **Results** - Active group showed 92.24% improvement in their lesions compared to 75.78% in placebo group - Mean time to improvement in Active Group was within 24 hours from the start of treatment, while this was found to be [illegible] days for the Placebo Group - Based on blinded evaluation, the PLRS scores for improvement were 87.07% and 64.8% in the Active and Placebo Arm respectively - PLRS scores also showed that the time to improvement in the active group was significantly faster in the Active Group - The resolution rate at the follow up time point for the lesions was 51.72% in the Active Group

#	Reference	Summary
		versus 36% in the Placebo Group - Subject's self assessment reported that the median time to improvement based on the VAS scale was 1 day in the active group versus 1.5 days in the placebo group. Time resolution based on subject assessment was no found to be statistically significant between the Active and Placebo groups - No device related adverse events that required medical attention or termination from the study were reported. **Conclusion** - No! no! Skin device is safe and effective in the treatment of mild to moderate acne lesions for all skin types - Treatment with the device provides statistically significant shorter lesion improvement and resolution rates. - Within 24 hours, there was 76.72% improvement in the active group compared to 15.63% in the placebo group - Treatment is most effective when applied early at the onset of the development of an acne lesion
11	Wheeland RG, Koreck A. **Safety and Effectiveness of a New Blue Light Device for the Self-treatment of Mild-to-moderate Acne.** J. Clinical Aesthetic Derm. 2012; 5(5):25-31 **Technology** Wavelength: 412 nm Source: LED Spot Size: 3 cm x 5 cm Treatment: Area A: 29 J/cm^2/day Area B: 2 J/cm^2/day	**Methods** • 32 subjects in total (21 female and 11 male) • Presenting with mild to moderate acne on face • Subjects required to have one target area on either their cheek, forehead or jawline containing 3-25 inflammatory lesions (Area A) and another target area containing (3-25 inflammatory lesions on opposite side of face (Area B) • Two treatments daily for 8 weeks (dose of 29 J/cm^2/day for Area A and lower dose of 2 J/cm^2/day for Area B) • Subjects evaluated by investigator for lesion count at all timepoints and by subject on appearance and improvements • Also at all post-baseline timepoints, subjects rated on satisfactory statements about blue light treatment and its results **Results** • 31 subjects completed study (1 discountined for nonstudy-related reasons) • Investigator assessed a median reduction in inflammatory lesion count at weeks 1,4,8 of 29,39,60%, respectively in Area A and 23,33,46% respectively in Area B. • At week 8, 100% of subjects reported improvement in overall appearance **Conclusion**

#	Reference	Summary
		• Blue light device treatment is effective for treatment of inflammatory acne • Majority of subjects reported either being satisfied, very satisfied, or extremely satisfied with blue light treatment
12	Gold, MH, Biron, JA, Sensing W. **Clinical and usability study to determine the safety and efficacy of the Silk'n Blue Device for the treatment of mild to moderate inflammatory acne vulgaris.** J. Cosmetic and Laser Therapy. 2013; Epub ahead of print: Early Online:1-6 **Technology** Wavelength: 405-460 nm Source: 24 LEDs Spot Size: Treatment Zone: 10 minutes per treatment zone 3 Zones for Treatment Left Side of Face Right Side of Face Forehead	**Methods** • 17 subjects in total (4 withdrew, 11 female and 1 male) • Mean age of 38.75 years old; presenting with mild to moderate acne on face • Two treatments per week for 4 weeks • Subjects self-treated under supervision for 10 minutes per zone, 3 facial zones (left, right and forehead) • Subjects evaluated using before and after photos to assess improvement via count of acne lesions by investigator and by subject satisfaction • Assessments were also made 1 and 3 months post 8 treatments **Results** • Decrease in mean acne count from baseline from 16.33 to 10.58 at 1 month follow up and 6.45 at 3 month follow up • 91.6% of subjects were satisfied with the treatments received • No occurrence of adverse events throughout the study • 100% of subjects were able to comprehend the labeling instructions provided **Conclusion** • The device significantly reduces the occurrence of mild to moderate forms of acne on the face following 8 bi-weekly treatments up to 3 months post the last treatment

Table 7: Scoring of Literature Reviewed based on Suitability Criteria

Reference to Article in Table 6	Appropriate device	Appropriate application	Appropriate patient group	Data source type	Outcome measures	Follow up	Statistical significance	Clinical significance	Final score/Comments
1	2	2	3	3	3	3	3	3	**22**
2	1	2	3	2	2	3	3	3	**19-** No placebo group or blinded evaluations.
3	1	3	3	3	3	3	3	3	22
4	1	3	3	3	3	2	3	3	21
5	2	3	1	2	2	2	3	2	**17-** Single ethnic

Reference to Article in Table 6	Appropriate device	Appropriate application	Appropriate patient group	Data source type	Outcome measures	Follow up	Statistical significance	Clinical significance	Final score/Comments
									population and short follow up time
6	2	3	2	2	2	2	3	1	**17-** Follow up was optional and no placebo or blinded evaluation.
7	2	3	3	1	2	3	3	2	19- No placebo or blinded evaluation. Did not include mean time to improvement
8	1	3	1	1	2	1	3	1	13- Single ethnic population, no follow up, no placebo or blinded evaluation
9	1	3	2	2	2	1	3	1	**14-** No follow up, no placebo or blinded evaluation
10	1	3	3	2	3	1	2	2	**17-**No follow up, no significance in subject assessment
11	2	3	3	2	2	1	3	2	**18**- No follow up, no placebo and comparison of cleanser with or without blue light for efficacy
12	2	3	3	2	2	3	3	3	**24-** Small patient

Reference to Article in Table 6	Appropriate device	Appropriate application	Appropriate patient group	Data source type	Outcome measures	Follow up	Statistical significance	Clinical significance	Final score/Comments
									population and no controls.