# Summary of safety and effectiveness

In accordance with Section 513 (1) of the SMDA as defined in 21CFR part 807.3, this summary is submitted to obtain Pre-market 510 (K) notification.

## 1. Submitter

JAN 1 4 2011

Ahwon Medi Instrument
Mr. Young Lee, President
187-7 Dodang Dong, WonMi gu,
Buchen, Kyunggi do, Korea 420 806
Tel: 32 670 7381 Fax 32 670 7383
e mail: ychi61@msn.com

## 2. U.S Agent / Contact person.

Mr. Young Chi, President
Bio-Med USA Inc ( Reg Nr. 2246683 )
111 Ellison street,
Paterson, NJ 07505. U.S.A
Tel: 1 973 870 2361 Fax 201 934 6030
e mail: biomedusa@msn.com

## 3. Name of Device

| | | |
|---|---|---|
| Trade name | : | RPL™ System, R2PL ™ System |
| Classification name | : | Powered, light based Non Laser Surgical Instrument with thermal effect |
| Common or usual name | | Intense Pulsed Light System |
| Regulation | : | 880.4810 |
| Class | : | II |
| Product code | : | ONF |

## 4. Substantial Equivalence ( Identification of legally Marketing device )

**Predicate device**

| | |
|---|---|
| GSD IPL System | K091664 |
| StrataPulse IPL system | K090837 |

The Ahwon's RPL, R2PL system are substantially equivalent with other already cleared and marketing device at design, function, intended to use, treatment profile and performing.

## 5. Device Description.

The Ahwon's RPL, R2Pl are IPL ( Intense pulsed light) system, using visible rays created by Xenon Lamp through Sapphire which are installed on Hand Piece, and composed

Main Board, unit
LCD monitor controlled by computer
Hand pieces
Cooling system

This device uses computer controlled Power supply and filter to generate light pulses of prescribed duration, intensity and spectral distribution. This device also equipped the Cooling systems to maintain both the Treatment head / Systems at appropriate and safe temperatures.,

The light pulses or emission spectra provide therapeutic indications relevant to specific wavelengths emitted from the system.

This system has two hand pieces and each hand piece has 2 wavelengths to choose from.
at the end of the Hand Piece, there is a sapphire filter and light is emitted when the button is pressed.

And manufactured in accordance with both mandatory and voluntary standard included

IEC60601-1 Medical Electrical equipment-part 1, General requirement for safety amendment 2.1995
IEC60601-1-2 Electro magnetic compatibility test ED 2:2001 Amendment 1 : 2004
ED2:1 Consolidated with amendment 1:2004

**General Description attached**

## 6. Intended use/Indication for use.

The Ahwon RPL, R2PL system intended use for in Surgical, Asthetic and Cosmetic Application in Dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV.

| Treatment | Wave length | |
|---|---|---|
| | RPL | R2PL |
| Acne, Vulgaris | | 415nm-950nm |
| Melasma, Ephelides. | 560nm-1200nm | 560nm-950nm |
| P.W.S/ Rosacea | 590nm-1200nm | 590nm-1200nm |
| Melasma/ | 640nm-1200nm | 640nm-1200nm |
| Hair Removal/ Vascular Lesions | 695nm-1200nm | 695nm-1200nm |

## 7. Conclusion

The Ahwon RPL/R2PL Intense Pulsed Light system, in this submission, is substantially Equivalent to several already cleared Predicate Device in respect to intended use, function, Technology, Principal operation and Performance.

So, it does not raise any additional concerns regarding safety and Effectiveness.

End of summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ahwon Medi Instrument Co., Ltd.
% Bio-Med USA Inc.
Mr. Young Chi, President
111 Ellison Street
Paterson, New Jersey 07505

JAN 14 2011

Re: K102857
Trade/Device Name: Ahwon IPL System – Model RPL, R2PL
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: December 30, 2010
Received: January 04, 2010

Dear Mr. Chi:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indication for use statement

510 (K)number : K102857

Device name : Ahwon IPL system model RPL, R2PL

Indication for use : The Ahwon RPL, R2PL system intended use for in Surgical, Asthetic and Cosmetic Application in Dermatology by using filtered Intense Pulsed Light to treat the following conditions with different wavelengths to skin types I-IV.

| **WaveLengths** | **Model RPL** | **WaveLengths** | **Model R2PL** |
|---|---|---|---|
| | | 415-950nm | Acne, vulgaris, |
| 560-1200nm | Melasma,Ephelides | 560-950nm | Melasma, Ephelides |
| 590-1200nm | Port wine stains, Rosacea | 590-950nm | Port wine stains, Rosacea |
| 640-1200nm | Melasma, | 640-1200nm | Melasma, |
| 695-1200nm | Hair reduction/removal<br>Vascular lesions. | 695-1200nm | Hair reduction/ Removal<br>Vascular lesions. |

Prescription use _____X_____ or / and Over the counter use_____
(Part 21 CFR 801 Sub part D) Part 21 CFR801 Sub part C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUED ON ANOTHER PAGES IF NEEDED

---

Concurrence of CDRH, office of Device Evaluation (ODE)

Neil R. Ogden for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102857