

Touch Screen Control Attendant Free Operation 15-20 Minute Sessions Look & Feel Years Younger! Treats Wrinkles, Blemishes, Age Spots, Stretch Marks, Crepe Skin and More!

Use on the Entire Body Contours to Body Shape Portable, Easy to Operate

#### K180875

Trade/Device Name: Poly Rejuv

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

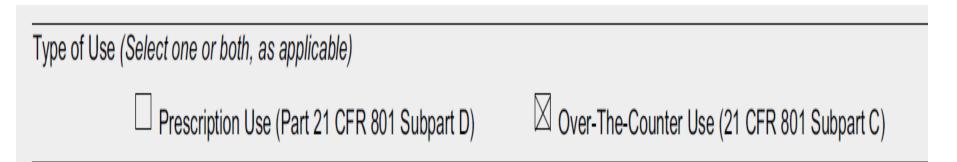
Product Code: OHS

Dated: March 16, 2018 Received: April 3, 2018





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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database

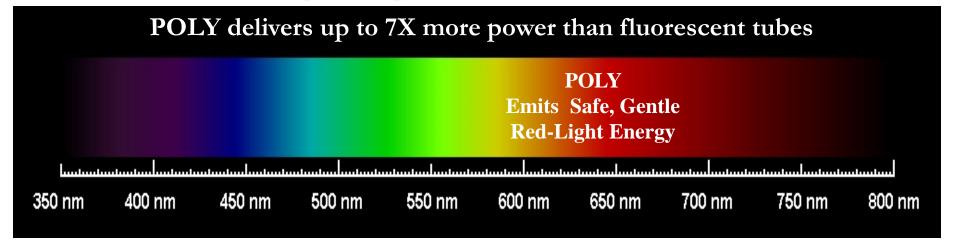


## **Every Body Loves POLY!**

### Thousands of POLY Systems in Use Worldwide

- Tanning Salons, Day Spas, Dermatologists, Plastic Surgeons, Chiropractors, etc.
- POLY can be used by all skin-types and body types. No age restrictions. Customers under age (18) have parental permission.
- POLY is safe, gentle and effective. Non-invasive. No down time or recovery time. Enhances healing process.
- Protective eyewear, though not required, is recommended for first time users and those sensitive to bright light.
- POLY can be used everyday. Recommend 2-3 sessions per week for 4-8 weeks. 1-2 sessions per week to maintain results.

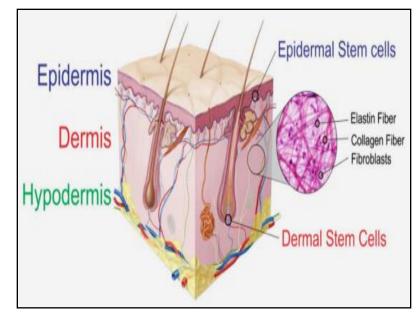
#### How Red-Light Energy Works To Rejuvenate the Skin!



Every cell in your body requires energy in the form of ATP (adenosine triphosphate) to function. ATP is manufactured and stored within cells called the mitochondria. As we age and cells become damaged the mitochondria is less able to efficiently produce ATP; which in turn effects the production of healthy collagen and elastin.

POLY's 1,820 LED lights generate Red-Light Energy within the precise wavelengths and power range required to safely and effectively stimulate the mitochondria to manufacture more ATP. As the Red-Light Energy gently passes through the cells it affects the flexibility and thickness of the intracellular fluid. The result is a reduction in the appearance of fine lines and wrinkles as well as softer, smoother, younger looking skin and a more vibrant complexion.

Fine lines and wrinkles on the surface of the skin are reduced in size and appearance by the natural stimulation of the collagen and elastin cells located beneath the skin's surface.



# POLY Pro Rejuv Red-Light Sales & Marketing Strategies / Product Highlights

- POLY has virtually 'zero' operating cost per session.
- 1,820 LEDs have a rated life of 50,000 hours. This equals **150,000**, 20-minute sessions. 12 sessions per day = **30 years**
- Electrical cost per session is less than **5 cents**.
- Each session / package sold generates pure profit.
- Attendant free operation. No additional labor cost to operate. Staff can perform other duties while customers are using POLY.
- POLY moves easily from room to room and can be used with a massage table, massage chair, aqua massage or sauna pod.

### **POLY Pro Rejuv Red-Light**

Sales & Marketing Strategies / Maximum R.O.I.

## Annual Revenue / Profit Target: \$20,000.00

- (1) Session = \$25.00
- (5) Sessions = \$75.00
- (30) Days Unlimited Use = \$49.00
- (1) Year of Unlimited Use = \$299.00
- While beautiful skin is the end result of using POLY, the raw commodity that we are selling is **TIME.**
- Create pricing structure that steers customers into purchasing packages that achieve **fantastic results** -- while you achieve **your financial goals**.
- When selling a 'cost-free / labor-free' service focus on generating the maximum level of 'dollars-per-customer-per-year'.

## POLY Pro Rejuv Red-Light Sales & Marketing Strategies / Maximum R.O.I.

### Annual Sales Target: \$20,000.00 - \$30,000.00

- Since POLY has virtually zero cost per operate per session, every session and package sold is pure profit.
- To generate **\$20,000.00** in profit per POLY per year, you simply need 100 customers to spend an average of \$200.00 per year. Or 200 customers spending \$100.00 per year.
- For example, charging just \$25.00 per month for Unlimited Use of POLY on an *annual membership* would generate \$300.00 per customer per year. **\$300.00 X 100 Customers = \$30,000.00**.
- Based on experience, customers purchasing monthly and annual packages actually use POLY 6-8 times per month.

## POLY Pro Rejuv Red-Light Sales & Marketing Strategies / Maximum Usage

- Since it takes 4-8 sessions within the first few weeks to see results, you want customers to use POLY frequently. Therefore you should offer 'POLY packages' that encourage frequent usage while also offering your customers a solid, affordable value.
- You also want to sell 'POLY packages that generate revenue regardless of how often the customer actually uses POLY.
- When you sell *only* by the 'session' customers often cannot make it to the spa due to traffic, obligations, etc. Not using POLY according to the recommended schedule will limit results.
- POLY can also be used on other parts of the body including the stomach, hips, thighs, etc.

# POLY Pro Rejuv Red-Light Bundling & Cross Promotional Strategies

- POLY can also be an effective marketing tool to help sell everything you offer.
- Skin care, supplements, CBD, etc., Rather than lowering prices offer Free TIME on POLY.
- For example, purchase a bottle of skin care product for \$50.00 and get (1) month of POLY Free. In essence you have provided a \$50.00 discount that in reality only costs you TIME.
- Furthermore, to redeem their discount, the customer must patronize your business over and over.
- The same strategy can be applied to other services. Avoid lowering prices. Simply provide more (labor-free) services!





Natural, Non-Invasive Skin Rejuvenation System



Moves Effortlessly Lock When Needed



Flexible Wide Body Panels 1,820 Long-Wave, LED Red-lights



Hands-Free, Attendant Free Operation Tremendous Labor & Cost Saving Feature



Password Protected Touch Screen Sets, Controls & Records Operations



**Articulating Arm Adjusts Panel Height & Direction** 



Soothing, Relaxing Experience Power Nap, Listen to Music



Use Anywhere on the Body 50,000 Hours of LED Power!



### Safe for All Skin Types

- Drug, Laser and Chemical Free
- Non-Invasive, Gentle & Relaxing
- No Down-time or Recovery-time
- Lasting Results
- 15-20 Minute Sessions



### Rejuvenates Skin Naturally

- Stimulates Collagen, ATP Production
- Reduces Fine Lines and Wrinkles
- Use on the Entire Body
- Lifts, Firms, Tones and Repairs!
- Age Spots, Stretch Marks, Crepe Skin
- Results in 4-8 Sessions



#### Year Round Profit Center

- Attendant Free Operation
- Operates for Pennies per Session
- 2-Year Parts & Service Warranty
- Easy to Use & Operate
- Increases Skin Care Product Sales
- Creates New Customers

















