

SkinPen® was first to market with the granting of DeNovo DEN160029, a submission requesting the creation of a Class II designation for motorized microneedling devices in the US and was cleared based on its *dependability* and *safety* when evaluated. After collaborating with leading experts in the medical aesthetics industry, Bellus was able to implement measures to prevent risks to both healthcare providers and consumers. "The FDA-clearance for SkinPen Precision demonstrates our brand's unwavering commitment to the safety, quality and excellence needed to elevate the standards in the microneedling industry," said Joe Proctor, Founder and President of Bellus Medical. "This recognition comes from the FDA, the highest organization in the US. With that, healthcare providers and consumers recognize they can trust SkinPen Precision to create, develop and manufacture the safest and most cutting-edge solutions on the market." To receive this FDA designation, SkinPen proactively worked through a rigorous three-year evaluation process to meet more than 90 validated requirements for the microneedling device, charger base and proprietary cartridge, including extensive biocompatibility testing to ensure none of the materials are harmful to patients' skin. SkinPen has also received a CE Mark, which indicates conformity with health, safety, and environmental protection within the European Union.

As you know from recent news, this is not the case with many other microneedling device companies on the market. Especially those who have been targeted by the MHRA and FDA. In addition to the cessation of sales, many have had previous issues with recalls, lack of inventory, challenges with customer service, ultimately leaving medical practices without recourse. **SkinPen** delivers a best in class level of customer service, training, and marketing support. This is validated by a recent survey in which 96% of our customers expressed a high overall satisfaction.