April 22, 2020

RE: Series 12 Elite, invisa-RED Technology

Dear

At its April 16, 2020, meeting, the Alabama Board of Medical Examiners (“the Board”) considered your request for an opinion concerning the application of Board Rules, Chapter 540-X-11, Guidelines for the Use of Lasers and Other Modalities Affecting Living Tissue, to the use of the Series 12 Elite device manufactured by invisa-RED Technology. The Board also considered the information you provided concerning the device.

The Board is of the opinion that, because the Series 12 Elite device affects living tissue, the use of the device to treat a physical disease, disorder, deformity, or injury constitutes the practice of medicine. Ala. Admin. R. 540-X-11-.03(1). Accordingly, the device may only be used for surgical, therapeutic, or cosmetic purposes by or at the direction of a physician licensed to practice medicine in Alabama, unless an exception applies. For a list of exceptions, please see Ala. Admin. R. 540-X-11-.01(3).

Sincerely,

ALABAMA BOARD OF MEDICAL EXAMINERS

E. Wilson Hunter
General Counsel

EWH: