

WHAT THE FDA EXPECTS FROM OUR INDUSTRY: REQUIREMENTS FOR PRINTED APPLIANCES



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Sponsor: Evo 820

CE: 1 Regulatory Standards

In this presentation we will address the misinformation that has been widely spread and the truth about how the incorporation of automated manufacturing processes into your dental laboratory have changed the FDA's view of dental labs and their present establishment exemption CFR 807.65(i). I will detail the FDA requirements that are now new to these CAD/CAM dental labs and how the processing, either subtractive or additive, have impact on you and the FDA requirements.

Tim has over 40 years experience in the dental industry with the past 30 years dedicated to the restorative processes involving dental implants. He has a diverse experience with medical device manufacturing, sales, management, and regulatory affairs. Tim brings his regulatory experiences from his time at Attachments International, Glidewell Dental Laboratories, and most recently Integrated Dental Systems, where Tim oversaw the development of five implant systems through design, production, and their regulatory process.

Tim is one of those rare individuals that not only has the creativity and foresight to expand business opportunities, he also has the ability to implement, execute, and manage projects to ensure his vision is met if not exceeded.