bility of brain damage that would be considered a severe adverse event is the reason this orthosis is a Class II device.

Manufacturers of CROs
As of January 7, there were 45 premarket notifications for CROs filed with the FDA. However, there are not 45 manufacturers of CROs on the market today. There are at least five central fabrication manufacturers: Orthomerica, Orlando, Florida; Hanger, headquartered in Austin, Texas; Danmar, Ann Arbor, Michigan; Boston Orthotics & Prosthetics, Avon, Massachusetts; and Cranial Technologies, headquartered in Tempe, Arizona. There are also some clinics that have clearance to manufacture CROs onsite, such as Cranial Solutions, Pompton Lakes, New Jersey, and Eastern Cranial Affiliates, headquartered in Fairfax, Virginia. The high cost of completing a 510(k) application ($10,953 or $2,738 for a small business reporting less than $100 million gross sales last fiscal year) as well as the mandatory quality systems, oversights, post-market surveillance, and site visits/audits from the FDA prevent most clinics/central fabrication centers from being able to manufacture CROs onsite. However, the FDA only regulates CRO use in the United States. Foreign countries may not have the same regulations. This is important to bear in mind when reading the literature on CRO treatment. CROs produced and utilized under foreign regulations do not necessarily reflect the efficacy of their use in the United States.

CROs are important medical devices and are one of the most highly regulated O&P items. They serve to correct head shapes by redirecting future growth. They do carry a miniscule risk of brain damage, which is well mitigated through guidelines set forth by the FDA and close clinician follow-up. Clinicians and the FDA have the same goal for these orthoses—to keep patients safe. The FDA does so through regulations of medical device manufacturers while clinicians carefully fit and monitor the use of these devices. The overarching goal of achieving a corrected head shape is not possible without both parties working in harmony. Having an increased knowledge of the regulation of CROs for manufacturers will allow you as an O&P professional to more easily communicate with manufacturers and better understand their responsibilities.

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