

StarFish Analysis: FDA lists 21 Class III products as reclassification candidates



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In 2014 the FDA reviewed 69 percent of the class III product codes and recently listed 21 as candidates for reclassification to class II. The reduction in cost from a class III to a class II submission along with the reduction in ongoing post market costs means there will likely be a spike in submissions for many of these types of devices.

One of these is product code MYN, analyzer, medical image. To date this has been restricted to mainly mammography analysis software but this will probably be extended to other types of diagnosis as the reduced costs makes these products more viable.