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The DensiCHEK Plus has applications as an in vitro diagnostic medical device. The intended use of the DensiCHEK Plus, as described in its labeling (DensiCHEK Plus Instrument User Manual), has not changed as a result of this modification to add VITEK 2 AST-YS to the list of products appropriate for use with DensiCHEK Plus now that performance ...

510(k) SUMMARY DensiCHEK TM Plus Special 510(k): Device ...

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