Osteoporosis is a widespread problem with increasing cases as baby boomers increase in age. Injuries due to falling have costs in excess of $17 billion associated with them and cause significant quality of life issues for elderly patients. Having a more convenient method of testing for osteoporosis will increase early detection and decrease associated costs of the disease. Our device will use a small blood sample to detect alkaline phosphatase levels, which will be correlated to bone turnover rates in patients. An immunoassay with magnetic beads will be encapsulated in a disposable device that will be cheap, portable and easy to use for elderly patients. Current methods, such as DEXA scans, are expensive, must occur in a doctor’s office and are time consuming. Our device will improve upon this by being disposable and easy to use.

Design Requirements: Affordable, Accurate, Portable, Ease of Use and Clear Readout

Market Analysis
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Executive Summary
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Problem and Clinical Need
- Osteoporosis is the loss of bone density by which the bones lose optimal mass and strength.
- Affects 1 in 3 women and 1 in 5 men.
- Can occur due to excessive bone reabsorption and inadequate response to increased bone reabsorption.
- While osteoporosis cannot be cured, it can be retarded by: exercise, diet and medicine.
- Diagnosis of the disease allows preventative treatment to save money and increase quality of life.
- Current Standards: DEXA scan and an X-Ray.
- Total costs including prevalent fractures are more than $19 billion. This number will only continue to grow as the generation of baby boomers becomes older.
- Estimated that by 2020, bone loss will affect 60 million citizens over 50.
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What is Novel About the Device?
- Measures bone turnover rate using Alkaline Phosphatase biomarker.
- Small and portable hand-held at-home test.
- Easy-to-use in terms of self-poking and magnified readout.
- Disposable.
- Affordable and available to a large population.

Estimation of Product Costs
- OsteoTest is estimated to cost $2.67 per device (without Cost of Machinery).
- Cost of Machinery is $10,000 (one time purchase).
- Cost of Unit at Bulk
  - 10,000 Units - $3.70 per device
  - 100,000 Units - $2.77 per device
- Profit
  - Product Selling Base Price - $10 per device
  - Profit per 10,000 Units - $63,000
  - Profit per 100,000 Units - $723,000

Anticipated Regulatory Pathway
- Class II medical device.
- Novel device: no predicate device exists in market.
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- Require Premarket Approval (PMA).
- Needs valid scientific evidence; target post-menopausal women.
- Must be reviewed by CBER.
- Blood samples from human clinical studies proves functionality.

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