

## **Example: Regulatory and Reimbursement**

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**This document provides information about regulatory strategies, clinical trial designs, and reimbursement alternatives for the stent apposition detector example used throughout this course.**

The FDA approval of drug-eluting stents (DES) is widely expected to revolutionize patient care, with industry estimates predicting 82% DES penetration into the US market by 2005<sup>1</sup>. These stents promise to significantly reduce or eliminate the problem of restenosis, but early studies show an 8.5% incidence of late stent mal-apposition in DES recipients<sup>2</sup>. If this proves to be a clinical problem, our device could also be used to non-invasively monitor stents for late mal-apposition without the need for catheterization.

### ***Regulatory Strategy***

This device would likely be regulated under CFR section 870.1425 as a programmable cardiovascular diagnostic computer, and would therefore be a Class II medical device. Since no part of the device enters the body, the only safety concern is the radiofrequency energy penetrating the body. Previous FDA approvals for MRI, neurostimulators, and programmable pacemakers have amply defined safe limits for specific absorbed RF radiation, and this device will easily fall within those limits. In addition, these previously approved devices should serve as predicate devices to which we can demonstrate substantial equivalence for a 510(k) approval pathway.

### ***Clinical Trial Design***

To make the FDA approval process as rapid as possible, the initial clinical indication that will be pursued is “noninvasively detects the presence of incomplete stent apposition arising during the three-month interval immediately following the implant of a drug-eluting stent.” Patients with preexisting stents or other metallic implants will be excluded from the clinical trial, as will those receiving more than one drug-eluting stent. In order to show the relative efficacy of the device, 800 patients will need to be enrolled. Given an expected 8.5% incidence of mal-apposition, around 68 positive detections can be expected at 3-month follow-up. For validation purposes, each study patient will also be subjected to invasive angiography and intravascular ultrasound at follow-up.

### ***Regulatory Timeline***

If we are able to show substantial equivalence to one of the aforementioned predicate devices, we believe that this approval will require only 6 months from the time of full enrollment to 510(k) approval. Because of the large number of trial participants, enrollment may require up to 12 additional months. Thus, we project an 800-patient trial requiring up to 18 months to complete.

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<sup>1</sup> Deutsche Bank Medical Supplies & Devices Report, 2002

<sup>2</sup> Published data from SIRIUS trial

## ***Reimbursement***

Currently, no reimbursement code exists for use of such a diagnostic tool in a visit to the clinic or in the catheterization lab. We believe that insurers will be eager to support this device, as this device provides a low-cost, noninvasive diagnostic in an area where no such solution currently exists. Therefore, our first priority will be to provide CMS with data (gathered with our FDA clinical trial) demonstrating the low cost of our device per life-year saved. In addition, because of the significant negative publicity that drug-eluting stents have received in 2003 due to the relatively high rate of subacute thrombosis, we believe that stent manufacturers may be eager to see our device approved. Their support could fund additional cost-benefit studies to further support our request for reimbursement. Alternatively, this device could be marketed by the stent manufacturers themselves and provided as part of a stent supply contract; in this case, the stent manufacturer would benefit by being able to claim lower morbidity and mortality rates associated with their stents (when used with the provided diagnostics).