

CALIFORNIA STATE BOARD OF EQUALIZATION
APPEALS DIVISION BOARD HEARING SUMMARY

In the Matter of the Claim for Refund)
Under the Sales and Use Tax Law of:)
PROVIDENCE HEALTH SYSTEM – SO CAL,) Account Number SR Y AS 16-085707
dba Little Company of Mary Hospital) Case ID 578178
Claimant) Torrance, Los Angeles County

Type of Business: Hospital
Claim period: 10/01/08 – 03/31/11

<u>Item</u>	<u>Claimed Refund</u>
Tax paid on purchases of breast tissue markers	\$7,151

Claimant filed a claim for refund for use tax paid to its vendor on purchases of breast tissue markers.

UNRESOLVED ISSUE

Issue: Whether claimant’s purchases of breast tissue markers are subject to tax. We find that they are and that no refund is warranted.

Claimant operates a hospital and has held a seller’s permit since December 1959. During the period October 1, 2008, through March 31, 2011, claimant paid use tax to New Jersey-based vendor C.R. Bard, Inc. on claimant’s out-of-state purchases of UltraClip Breast Tissue markers and UltraClip Dual Trigger Breast Tissue Markers (collectively, BTM’s) for use in its hospital. These BTM’s are sterile single-use (i.e., disposable) medical devices that are comprised of an introducer needle and applicator (together, applicator), as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. The applicator inserts a marker into soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site so that it can be accurately identified by ultrasound, MRI, or other imaging methods at a future date. The markers are made of titanium or a metal alloy, and take the shape of a ribbon, wing, or coil to differentiate multiple biopsy sites. The U.S. Food and Drug Administration (FDA) regulates the sale of the BTM’s at issue and has classified them as Class II medical devices.

1 Claimant has filed a claim for refund¹ contending that BTM's qualify as medicines and that
2 claimant purchased and furnished the BTM's in an exempt manner as specified in California Code of
3 Regulations, title 18, section (Regulation) 1591, subdivision (d)(1)-(6). Claimant makes three main
4 arguments or analogies. First, claimant argues that the intent of the relevant authorities is to exempt
5 from taxation the purchase or use of *anything fully implanted or injected in the human body*² when
6 approved by the FDA for the purpose of diagnosing, curing, mitigating, treating, or preventing any
7 disease, illness, or medical condition. Claimant asserts that the BTM's qualify as medicines because
8 they are used directly in diagnosing and treating breast cancer. Claimant further states that there is no
9 distinction between breast implants and BTM's, and claimant thus reasons that there should be no
10 difference in the tax treatments of those items. Second, claimant argues that BTM's are analogous to
11 x-ray dyes and opaques, the use of which is exempt from taxation. Third, claimant asserts that BTM's
12 are Class III medical devices like breast implants, and breast implants are considered medicines.
13 Alternatively, claimant argued in a Request for Reconsideration (RFR) that the phrase "approved by
14 the U.S. Food and Drug Administration" in Regulation 1591, subdivision (a)(9)(A) is not specifically
15 referring only to the FDA's premarket approval process for Class III medical devices, but rather
16 references a more broad and generic FDA approval, including premarket notification for Class II
17 medical devices such as BTM's.

18 With respect to claimant's first argument, we find, based on the Board's intent (as more fully
19 described in the SD&R) and absent further guidance from the Board, that Regulation 1591,
20 subdivision (a)(9)(A), is intended to exempt fully implanted or injected Class III medical devices,
21 which are subject to the FDA's premarket approval process. The BTM's are Class II medical devices,
22 which, although fully injected into soft breast tissue, do not require the FDA's premarket approval.

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25 ¹ Claimant's correspondence, dated August 1, 2011, originally encompassed refund claims for claimant and three other
26 facilities it operates: (1) St. Joseph Medical Center in Burbank, California (SR Y AC 13-019544, Case ID 578177);
27 (2) Providence Holy Cross Medical Center in Mission Hills, California (SR X AC 97-235776, Case ID 578178); and
28 (3) Providence Little Company of Mary Medical Center in San Pedro, California (SR EA 100-870707, Case ID 578190).
All four claims involve tax paid on its purchase of BTM's. Claimant requested that one claim proceed through the appeals
process as the lead case, with the others held in abeyance. The claim at issue here is that lead case.

² Claimant provided some clarification regarding this assertion in its Request for Reconsideration (RFR), and we address
here claimant's clarified position. Also, in the RFR, claimant asserts that some of the conclusions in the D&R are
erroneous. Accordingly, with respect to those issues, the analysis herein relates primarily to the analysis in the SD&R.

1 Instead, Class II medical devices, like BTM's are subject to premarket *notification*, in which device
2 manufacturers must demonstrate to the FDA that the device to be marketed is at least as safe and
3 effective or substantially equivalent to a legally marketed device that is not subject to premarket
4 approval. Accordingly, we conclude that BTM's do not qualify as medicines under Regulation 1591,
5 subdivision (a)(9)(A). We further conclude that the BTM's do not qualify as medicines under the
6 supplemental definition in Regulation 1591, subdivision (b)(2), because they do not assist the
7 functioning of any natural organ, artery, vein or limb. On that issue, we find that the primary issue is
8 not whether the devices remain in the body for an extended period but whether they also replace or
9 assist the functioning of a natural part of the human body. In other words, we find that permanent
10 implantation standing alone is not enough to conclude that a device qualifies as a medicine.

11 With respect to claimant's argument that BTM's are analogous to x-ray dyes and opaques, we
12 note that the markers are not ingestible. Further, unlike dyes or opaques, the markers are classified as
13 medical devices. Accordingly this argument lacks merit. Regarding claimant's third argument, that
14 BTM's are Class III devices like breast implants, which are considered medicines, we first note that
15 BTM's are Class II devices which do not require premarket approval by the FDA. In contrast, the
16 BTM's are intended to mark a site for radiographic imaging purposes. Thus, claimant's third argument
17 also lacks merit.

18 **OTHER MATTERS**

19 None.

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21 Summary prepared by Deborah A. Cumins, Business Taxes Specialist III
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