

**STATE OF CONNECTICUT**  
DEPARTMENT OF PUBLIC HEALTH  
*Office of Health Care Access*

August 25, 2010

**IN THE MATTER OF:**

An Application for a Certificate of Need filed pursuant to Section 19a-639, C.G.S. by:

Notice of Final Decision  
Office of Health Care Access  
Docket Number: 10-31537-CON

**Dennis Gianoli d/b/a Dennis Gianoli, DDS,  
P.C.**

**Acquisition and Operation of a Cone-Beam  
Computed Tomography Scanner in Berlin**

To: Dennis Gianoli  
Dennis Gianoli, DDS, P.C.  
5 Webster Square Road  
Berlin, CT 06037

Dear Dr. Gianoli:

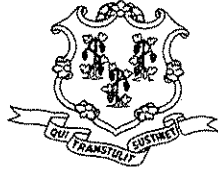
This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Section 19a-639, C.G.S. On August 25, 2010, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

A handwritten signature in black ink, appearing to read "Kimberly R. Martone", written over a horizontal line.

Kimberly R. Martone  
Director of Operations

Enclosure  
NDG:KRM:swl





**Department of Public Health  
Office of Health Care Access  
Certificate of Need Application  
Final Decision**

**Applicant:** Dennis Gianoli, DDA  
**Docket Number:** 10-31537-CON  
**Project Title:** Acquisition and operation of a Cone-Beam Computed Tomography Scanner in Berlin

**Project Description:** Dennis Gianoli, DDS ("Applicant" or "Practice") is proposing to acquire and operate a Cone-Beam Computerized Tomography ("CBCT") scanner in Berlin, Connecticut, at a total capital cost of \$117,562.

**Nature of Proceedings:** On May 26, 2010, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application for the above-referenced project.

A notice to the public regarding OHCA's receipt of the Applicant's Letter of Intent to file its CON Application was published in *The Herald* on February 15, 2010. OHCA received no responses from the public concerning the Applicant's proposal. Pursuant to Section 19a-639, C.G.S., three individuals, or an individual representing an entity with five or more people, had until June 16, 2010, the twenty-first calendar day following the filing of the Applicant's CON application, to request that OHCA hold a public hearing on the Applicant's proposal. OHCA received no hearing requests from the public.

OHCA's authority to review and approve, modify or deny this proposal is established by Section 19a-639, C.G.S. The provisions of this section as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

## Findings of Fact

1. The Applicant, a Oral and Maxillofacial Surgeon<sup>1</sup>, is a for profit dental practice located at 5 Webster Square, Berlin, Connecticut. *(April 22, 2010 Initial CON Application, page 2)*
2. The Applicant treats many types of dental and facial pathology, including: (1) exodontias, both simple and very complicated; (2) implant surgery; (3) pathology associated with the oral cavity, both bony and soft tissue; (4) facial deformities; and (5) trauma. *(April 22, 2010 Initial CON Application, page 7)*
3. Currently, the Practice utilizes a Panorex<sup>2</sup> unit and two dental x-ray units. *(April 22, 2010 Initial CON Application, page 10)*
4. The proposed CBCT scanner is a PaX-Duo3D manufactured by Vatech. The proposed scanner will provide the Applicant the ability to provide panoramic as well as CBCT scans. *(April 22, 2010 Initial CON Application, page 9-10)*
5. The population to be served would include patients with the following:
  - a Orthodontic considerations both pre-treatment and during treatment, e.g. definitive location of un-erupted teeth, and guidance in movements preventing root exposure;
  - b Complicated surgical exodontias, for localization of root apices and vital structures, e.g. the inferior Alveolar nerve;
  - c Implant cases for treatment planning in placement and angulations in viable bone formations; and
  - d Pathology in describing the location, size and density of bony lesions. *(April 22, 2010 Initial CON Application, page 11)*
6. The proposed CBCT scanner is a pan-limited field cone beam that will allow the Applicant to provide a considerably smaller amount of radiation exposure than a full CBCT or a traditional CT scanner. *(April 22, 2010 Initial CON Application, page 6)*
7. The proposed CBCT scanner will allow for more definitive treatment planning for complicated exodontias, pathology, implants, and trauma. *(April 22, 2010 Initial CON Application, page 7)*

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<sup>1</sup> Oral-Maxillofacial Surgery is a surgical specialty which involves the diagnosis, surgery and adjunctive treatment of diseases, injuries and defects involving both the functional and aesthetic aspects of the hard and soft tissues of the oral and maxillofacial region. Source: [www.umm.edu/omsurg/oral-maxillofacial.htm](http://www.umm.edu/omsurg/oral-maxillofacial.htm)

<sup>2</sup> A panorex is a two-dimensional dental x-ray that displays both the upper and lower jaws and teeth, in the same film.

8. Three dimensional imaging of cysts and tumors of the maxillofacial region can give the surgeon the vital information necessary for planning surgery with volumetric analysis. This can help anticipate the need for and volume of a potential graft for reconstruction. *(Queresby, FA., et al., Applications of Cone Beam Computed Tomography in the Practice of Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, 2008 Apr;66(4):791-6)*
9. Conventional CT is used routinely in the diagnosis of maxillofacial pathology. Given the higher resolution, lower radiation dose and lower cost of a CBCT scanner in imaging the maxillofacial region, it stands to reason that a CBCT scanner can easily replace a conventional CT scanner in this regard. *(Queresby, FA., et al., Applications of Cone Beam Computed Tomography in the Practice of Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, 2008 Apr;66(4):791-6)*
10. The advantages of CBCT in visualizing the alveolus in 3D and making precise measurements before surgery are obvious in the field of implant dentistry. Compared to a conventional panoramic radiography, it is not unusual to anticipate adequate bony support preoperatively, only to be disappointed in the reflection of tissue. *(Queresby, FA., et al., Applications of Cone Beam Computed Tomography in the Practice of Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, 2008 Apr;66(4):791-6)*
11. The identification, treatment planning, and evaluation of potential complications of impacted teeth are greatly improved by adding the third dimension through a CBCT scanner. The site evaluation becomes not only less invasive and less time-consuming, but also more complete. *(Queresby, FA., et al., Applications of Cone Beam Computed Tomography in the Practice of Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, 2008 Apr;66(4):791-6)*
12. The CBCT reformatted panoramic images were found to be superior to digital panoramic images for identification of the mandibular canal. The posterior third of the mandibular canal is better depicted regardless of observer and imaging modality. *(Angelopolous, C., et al., Comparison Between Digital Panoramic Radiography and Cone-Beam Computed Tomography for the Identification of the Mandibular Canal as Part of Presurgical Dental Implant Assessment, Journal of Oral and Maxillofacial Surgery, 2008 Oct;66(10):2130-5)*
13. The Applicant's historical total practice volume is as follows:

**Table 1: Practice's Total Historical Volume**

	2007	2008	2009
<b>Total Volume</b>	3,876	4,016	4,256

*(May 26, 2010, Completeness Letter Response, page 52)*

14. Currently, the patients of the Practice only have two choices: they can go to University of Connecticut Health Center ("Center") or they can go to a local hospital's traditional CT Scanner. *(April 22, 2010 Initial CON Application, page 7)*
15. The Applicant indicates that cases from the office have, at times, waited greater than 4 weeks for a scan, which is unacceptable particularly when a dangerous pathologic situation may need clarification. *(April 22, 2010 Initial CON Application, page 127)*

16. The Applicant’s historical total number of annual referrals for CBCT scans are as follows:

**Table 2: Annual CBCT Scan Referral**

	2007	2008	2009	FY 2010*
<b>Annual Referral</b>	104	121	119	204

\*FY 2010 has been annualized based on actual CBCT referrals between January-March, 2010 (51).  
(May 26, 2010, Completeness Letter Response, page 52)

17. OHCA finds that the Applicant, with an established practice in the field of oral surgery, has been achieving historical annual increases in its practice utilization. Further, referrals for CBCT scans have increased approximately 50% overall between 2007 and 2010.
18. The Applicant’s projected total practice utilization:

**Table 4: Practice’s Total Projected Utilization**

	FY 2010*	FY 2011	FY 2012	FY 2013
<b>Total Practice Volume</b>	4,300	4,450	4,600	4,750

\*FY 2010 annualized based on January-March, 2010 actual data (1,075).

Note: The Applicant based the total Practice volume projections on their increasing historical total practice utilization. (May 26, 2010, Completeness Letter Response, page 52)

19. The Applicant’s projected total number of CBCT scans are as follows:

**Table 5: Projected CBCT Volume**

	FY 2010	FY 2011	FY 2012	FY 2013
<b>Annual Referral</b>	204	220	235	250

\*FY 2010 Actual data between January-March, 2010 (51).  
(May 26, 2010, Completeness Letter Response, page 52)

20. The Applicant based the projected CBCT utilization on the number of implant cases, oral surgeries, teeth localization and fractures that the Practice performed last year.
21. OHCA finds that volume projections are reasonable and achievable based upon the Applicant’s historical practice utilization and referrals for CBCT scans.
22. The Applicant’s proposed target population for the proposed CBCT scanner is the Practice’s own patients and the Applicant would not accept referrals from other dentists and orthodontists. (May 26, 2010, Completeness Letter Response, page 53)
23. The proposed total capital cost associated with the acquisition of the proposed CBCT scanner is \$117,562. (April 22, 2010, Initial CON Application, page 36 and May 26, 2010, Completeness Letter Responses, page 55)
24. The Applicant submitted a letter from Bank of America that indicates the bank’s intent to lend the Applicant \$75,000, at 7.49% for a period of 84 months. (April 22, 2010, Initial CON Application, page 40)

25. The Applicant will pay the remaining balance of the cost by from the office account. *(May 26, 2010, Completeness Letter Response, page 56)*
26. The charge on the proposed CBCT scanner will be \$350 per scan. *(April 22, 2010 Initial CON Application, page 44)*
27. The Center charges \$450 per CBCT, and the Applicant can charge less due to decreased costs. *(April 22, 2010 Initial CON Application, page 44)*
28. The Applicant's incremental gains with the proposal indicate a consistent increase in income from operations:

**Table 7: Incremental Gains to the Project**

<b>Description</b>	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013</b>
Incremental Revenue from Operations	\$70,000	\$70,000	\$70,000
Incremental Total Operating Expense	\$13,880	\$13,800	\$70,000
<b>Incremental Gains from Operations</b>	<b>\$36,530</b>	<b>\$36,530</b>	<b>\$36,530</b>
<b>Overall Practice Gains, Incremental to the Proposal</b>	<b>\$43,824</b>	<b>\$42,354</b>	<b>\$42,936</b>

*(May 26, 2010, Completeness Letter Responses, Financial Attachment I, page 58)*

29. There are no losses associated with this proposal. *(May 26, 2010, Completeness Letter Responses, Financial Attachment I, page 58)*
30. OHCA finds that the Applicant's proposal is financially feasible based upon the Applicant's projections with respect to incremental and overall gains for the practice.
31. The Applicant will have to perform a minimum of 74 scans per year to show an incremental gain from operations as it related to this proposal. *(March 23, 2010, Initial CON Application, page 9)*

32. The following table illustrates the current and projected payer mix for the practice based on patient population:

**Table #: Current & Three-Year Projected Payer Mix for the Applicant**

	<b>Current FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013</b>
Medicare*	2%	2%	2%	2%
Medicaid*	0	0	0	0
Champus and TriCare	0	0	0	0
<b>Total Government</b>	<b>2%</b>	<b>2%</b>	<b>2%</b>	<b>2%</b>
Commercial Insurers*	64%	64%	64%	64%
Uninsured/Private Pay	34%	34%	34%	34%
Workers Compensation	0	0	0	0
<b>Total Non-Government</b>	<b>98%</b>	<b>98%</b>	<b>98%</b>	<b>98%</b>
<b>Total Payer Mix</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

\* Includes managed care activity  
*(April 22, 2010, Initial CON Application, page 42)*

33. If the diagnosis is dental in nature, the procedure will not be covered, at present, by any dental carrier. If the diagnosis is medical in nature, e.g. pathology or trauma, the medical carrier will provide coverage dependent upon the particular policy. *(April 22, 2010, Initial CON Application, page 44)*



## Rationale

OHCA approaches community and regional need for CON proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

The Applicant specializes in oral-maxillofacial surgery, which involves the diagnosis, surgery and adjunctive treatment of diseases, injuries and defects [Findings 1&2]. The Applicant currently utilizes a two-dimensional Panorex dental x-ray and two standard x-ray units. The Applicant proposes to acquire a PaX-Duo3D CBCT scanner, which will provide panoramic as well as CBCT scanning capabilities [Findings 4&7].

The proposed CBCT scanner will allow the Applicant to provide more definitive treatment planning for complicated exodontias, pathology, implants and traumas. The identification, treatment planning, and evaluation of potential complications of impacted teeth are greatly improved by adding the third dimension through a CBCT scanner. Further, the addition of three dimensional imaging of cysts and tumors of the maxillofacial region can give the surgeon the vital information necessary for planning surgery, anticipating the need for a potential graft for reconstruction [Findings 8, 9&12]. The proposed CBCT scanner is a pan-limited field cone beam that will allow the Applicant to provide a considerably smaller amount of radiation exposure than a full CBCT or a traditional CT scanner [Finding 6]. Accordingly, OHCA finds that the proposal will positively impact the quality and accessibility of health care delivery to the Applicant's patients.


The Applicant anticipates an increase in volume with respect to the proposal based on its historical annual practice utilization [Finding 14]. The Applicant is also projecting increasing annual CBCT scans for the first three years of the proposal based on the number of historical annual referrals to other imaging services providers for a CBCT scan [Finding 17]. OHCA finds that the volume provided by the Applicant appears to be reasonable based upon the historical utilization of the overall practice and annual CBCT scan referrals over the past three years.

The total capital cost associated with this proposal is \$117,562. The Applicant plans to lease the proposed CBCT scanner and finance the balance of the associated cost from office funds. The Applicant projects the following gains from net income for the overall practice for the first three projected years of the proposal of \$43,824, \$42,354 and \$42,936, for FYs 2011, 2012 and 2013, respectively and the fee associated for each CBCT scan is \$350 [Finding 26&24]. Based on projected rates and gains from operations, OHCA finds that the proposal is financially feasible [Finding 28].

## Order

Based upon on the foregoing Findings and Rationale, the CON application of the Applicant to acquire a dental CBCT scanner in Berlin, Connecticut, with an associated capital cost of \$117,562 is hereby **GRANTED**.

8.25.10  
Date

  
Norma Gyle, R.N., Ph.D.  
OHCA Deputy Commissioner

NG:swl